EXHIBIT

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN
THIS DOCUMENT RELATES TO: THE CASES LISTED BELOW	U.S. DISTRICT JUDGE
Mullins, et al. v. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.	2:12-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.	2:13-cv-07283

VIDEOTAPED DEPOSITION OF
ROBYN LYN PRUEITT, Ph.D., D.A.B.T.

Thursday, October 22nd, 2015
9:48 a.m.

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Oxley v. Ethicon, Inc., et al. 2:13-cv-10150

Atkins, et al. v. Ethicon, Inc., et al. 2:13-cv-11022

Garcia v. Ethicon, Inc., et al 2:13-cv-14355

Lowe v. Ethicon, Inc., et al. 2:13-cv-14718

Dameron, et al. v. Ethicon, Inc., et al. 2:13-cv-14799

Vanbuskir, et al. v. Ethicon, Inc., et al. 2:13-cv-16183

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Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664

Schepleng v. Ethicon, Inc., et al. 2:14-cv-16061

Tyler, et al. v. Ethicon, Inc., et al. 2:14-cv-19110

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DEPOSITION OF ROBYN LYN PRUEITT, Ph.D., D.A.B.T.

Held At:
Gradient Corporation
20 University Road
Cambridge, Massachusetts

REPORTED BY:
Maureen O'Connor Pollard, RMR, CLR, CSR

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Videographer: Christopher Coughlin

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E X H I B I T S

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Chris Coughlin, and I'm a videographer for Golkow Technologies. Today's date is October 22nd, 2015, and the time is 9:48 a.m..

This video deposition is being held in Cambridge, Massachusetts, In Re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation, in the United States District Court for the Southern District of West Virginia, Charleston Division.

The deponent is Robyn Prueitt, Ph.D, D.A.B.T..

Will counsel please identify yourselves for the record.

MR. ORENT: Good morning. Jonathan Orent for the Plaintiffs, I'm here with Dennis Costigan, also for the Plaintiffs.

MR. HUTCHINSON: Chad Hutchinson, counsel for Johnson & Johnson and Ethicon.

MS. LOWRY: Patricia Lowry for Defendant Johnson & Johnson and Ethicon.

THE VIDEOGRAPHER: The court reporter

is Maureen Pollard, and she will now swear in the witness.

ROBYN LYN PRUEITT, Ph.D., D.A.B.T., having been first duly identified and sworn, was examined and testified as follows:

EXAMINATION

BY MR. ORENT:

Q. We're getting a little bit late start today, I apologize to everyone. Traffic was unbearable. It took us over three hours to get here this morning from Providence, which is at least another hour plus than it should have taken. So I appreciate your courtesy.

Ms. Prueitt, would you state -- excuse me. Dr. Prueitt, would you please state your full name for the record?

A. Robyn Lyn Prueitt.

Q. And did you ever go by any other names, a maiden name, anything like that?

A. No.

Q. Are you currently married?

A. Yes.

Q. Ms. Prueitt -- excuse me.

Dr. Prueitt, I'm going to mark as

Exhibit 1 to today's deposition a copy of your report in this matter.

(Whereupon, Prueitt Exhibit Number 1, Dr. Prueitt's October 9, 2015 expert report, was marked for identification.)

BY MR. ORENT:

Q. Do you recognize this Exhibit 1 as being a report authored by you and dated October 9, 2015?

A. Yes.

Q. And does this contain a full listing of all of the opinions that you intend to express in this matter?

A. Yes, it does.

Q. This report is signed on October 9th. When is it that you were first retained by Ethicon in this matter?

A. October 2nd -- excuse me. October 1st.

Q. Had you ever done any work for Ethicon prior to October 1st?

A. No.

Q. Now, this was signed on October 9th. When did it become final in terms of the draft?

A. October 9th.

Q. So you were editing it and working on it up until the moment you signed it?

A. Yes.

Q. And prior to October 1st, what work had you done on medical devices?

A. None.

Q. How about medical implants?

A. None.

Q. When is the first time you evaluated testing using the ISO-10993 series tests?

A. For this case.

Q. This is the first time that you ever evaluated ISO-10993 type testing, is that right?

A. Yes.

Q. And when is the first time that you ever evaluated preclinical animal studies?

A. Just in general?

Q. In general.

A. I can't say. I've evaluated many such studies over the course of my time at Gradient in evaluating toxicity of various chemicals.

Q. Okay. So I used the term preclinical. Have you ever evaluated, prior to this case, an in vivo study of an implant?

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A. No.
Q. Prior to this, what types of in vivo animal studies did you look at?
A. All sorts of studies, acute studies to determine the acute toxicity, such as lethality studies, subacute studies of less than 30 days in duration of various chemicals by various exposure routes, subchronic studies, that is 90 day studies of various chemicals, and chronic studies, particularly carcinogenicity studies.
Q. And how far out -- what's the longest in time that you have seen animal studies go?
A. I've seen a few go past two years, though two years is the sort of standard amount of time.
Q. Standard for the work that you've done in the past?
A. Yes.
Q. And prior to your work -- I used the particular ISO protocol 10993 in my prior questions, had you done in vitro assay work prior to this case?
A. I have, although not under the ISO guidelines. But yes, in general I have done in vivo -- excuse me, in vitro studies.

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Q. Okay. What types of in vitro studies did you do previously?
A. Quite a few. In my past work I have -- I've added nicotine to prostate cancer cells to study their growth and potential tumorigenic properties after that exposure. I've used in vitro cells to extract protein, DNA or RNA for various molecular biology applications.
Q. Have you done any cytotoxicity studies, as you've defined the term in your report, previously in the in vitro context?
A. In general terms not, in the way that it's described in my report.
Q. How about in specific terms?
A. No.
Q. Now, you've been here at Gradient since 2008, is that correct?
A. 2007.
Q. 2007.
Before that, you worked at the Fred Hutchinson Cancer Research Center?
A. Yes.
Q. And before that, the National Cancer Institute, is that correct?

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A. Yes.
Q. Have you ever -- did you do any private consulting while working at Fred Hutchinson Cancer Research Center?
A. No, I did not.
Q. How about while at the National Cancer Institute?
A. No.
Q. So all of your private consulting began when you came to Gradient?
A. Yes.
Q. Now, I see that you have not testified in the last four years. Have you ever provided deposition testimony at all?
A. No, I haven't.
Q. So this is your first time?
A. Yes.
Q. Have you ever provided testimony in a trial?
A. No.
Q. Have you ever worked on -- strike that.
Have you ever sat in on a deposition?
A. No.
Q. Have you ever, prior to your

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preparation for this and prior to your retention to this case, ever worked to prepare someone for a deposition?
A. Yes.
Q. On approximately how many occasions?
A. Maybe two or three.
Q. And what context? What types of litigation was that involved in?
A. Let's see. I can't discuss specifically because they never -- the cases never went to trial, so I'm concerned about confidentiality.
Q. Okay.
A. But in general, toxic tort cases where there was exposure to a substance in air and claims of health effects.
Q. Okay. Can you tell me what that substance was?
A. I don't know if I can.
Q. Okay. You've done consulting on behalf of companies that formerly manufactured asbestos, is that correct?
A. Yes.
Q. And you've also done consulting on behalf of companies that manufactured tobacco

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products, correct?
A. Yes.
Q. And you've also done work for the American Petroleum Institute, is that right?
A. Yes.
Q. And you've also done work for individual manufacturers of petroleum products, gas products, correct?
A. Yes.
Q. And you've also done work for other companies that utilize benzene-based products, is that right?
A. Yes.
Q. And with regard to asbestos, you've worked -- or you've formed opinions as to whether or not chrysotile asbestos is a carcinogen, is that right? That's one of the questions you looked at?
A. Yes. I did not form opinions. I was in a supporting role. But yes, that is a question that was looked at.
Q. And ultimately, the person who was testifying that you worked for in that context concluded that chrysotile asbestos was not carcinogenic, is that right?

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A. Yes, I believe so.
Q. And that is contrary to what the World Health Organization has said about chrysotile asbestos, is that right?
A. I don't know.
Q. In assisting in that work, did you go to the World Health Organization's publications, like IARC, or any of the other World Health Organization publications to determine whether or not they believed that chrysotile asbestos was carcinogenic?
A. No, because my portion of the work really didn't involve that aspect.
Q. And did your portion look at the epidemiology related to workers who had been exposed to chrysotile asbestos?
A. No.
Q. Did it involve looking at lung tissue samples of individuals who had been exposed to chrysotile asbestos products?
A. No.
Q. And the context in which you were working on these cases was that your company, Gradient, had been hired by companies to demonstrate that the risk -- excuse me, to

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demonstrate that the individual complainant could not have developed mesothelioma as a result of exposure to chrysotile asbestos, is that right?
A. Yes.
Q. Now similarly, with regard to the work that you've done on benzene, you ultimately were retained by someone, a defendant in litigation, who wanted Gradient to provide testimony that said that benzene was not the cause of an individual complainant's cancer, is that right?
A. I believe so.
Q. And similarly, in the tobacco cases that you've worked on, the tobacco companies retained Gradient, and you assisted in preparing reports where ultimately the opinions of Gradient were that the tobacco was not a contributor to the individual's development of cancer, correct?
MR. HUTCHINSON: Object to form.
A. No.
BY MR. ORENT:
Q. No. Okay.
What was your role in the tobacco cases?

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A. It was very small. It was shortly after I started at Gradient, so I don't remember a lot of the specifics, but it had to do with comparison of light cigarettes to regular cigarettes.
Q. And ultimately, the conclusion there was that regular cigarettes have a more carcinogenic potential, is that right?
A. I don't know.
Q. And that was -- you were there retained on behalf of the Defendant in that tobacco litigation, correct?
A. I'm actually not clear if there was litigation. It may have just been consulting to understand the scientific issues better.
Q. Okay. And I see you also were retained in some lead litigation, is that correct?
A. Yes.
Q. And there you worked to determine that individual exposure to lead was not the cause of the injuries complained of by a group of individual children, is that right?
A. Yes, that's what the testifying expert was claiming.

Q. Okay. And one of the things that you're aware of is that lead has no known threshold below which there's not been seen to have been found an effect, is that correct?
A. That's debatable in the scientific literature.
Q. Okay. So you're aware that the CDC has taken the position that there is no threshold below which lead doesn't have an effect?
A. I think I've seen that statement.
Q. Okay. And you disagree with that statement?
A. I think that some of the work done here at Gradient may contradict that statement.
Q. Okay. And so what threshold have you worked on here at Gradient that shows that there is a threshold effect for lead?
A. I can't remember.
Q. Do you know, as you sit here today, do you recall what the threshold was that you all determined?
A. No, I don't remember.
Q. But certainly you are aware that individuals at Harvard, for example Phil

Landrigan, has done a lot of research that shows that, for example, at 3 micrograms per deciliter there's conclusive effects on individuals?
MR. HUTCHINSON: Object to form.
A. I don't know. I don't know that they're conclusive.
BY MR. ORENT:
Q. So you're also aware that the World Health Organization has formed statements on lead, correct?
A. I can't remember. I really didn't prepare to talk about lead today.
Q. Okay. But your opinion certainly, as you sit here today, is that you believe that there is a threshold for lead exposure, correct?
A. I believe that some of the scientists at Gradient have produced manuscripts in the peer-reviewed literature and other comments that indicate that there's likely a threshold.
Q. And who are those individuals that wrote those?
A. Barbara Beck, and Theresa Bowers.
Q. Now, Barbara Beck was retained by the Lead Industries Association, was she not?
A. I don't know who she was retained by.

Q. But she's done work in litigation, regardless, on lead poisoning?
A. Yes.
Q. And you as a scientist, do you put more weight and credibility into the work done by Barbara Beck and the individuals here at Gradient, or do you put more weight onto the CDC's statements in 1991 and 2005 and 2014, I think was the latest one?
MR. HUTCHINSON: Object to form.
A. Well, here we look at all the evidence, and so whatever the evidence that the CDC used as their basis we also examine, but we also examine the work of Barbara Beck as well. So, you know, it just depends on -- it's actually a large body of data. We evaluate a large number of studies and, you know, come to our conclusions based on that large body of data.
BY MR. ORENT:
Q. Okay. And just for the record, the American Academy of Pediatrics has also come out strongly in multiple iterations in the last 15 years suggesting that lead has no known threshold below which there are not -- negative

effects have been found, is that right?
MR. HUTCHINSON: Form.
A. I don't know.
BY MR. ORENT:
Q. Okay. But that would be contrary to the position that Gradient has taken as well, correct?
A. Yes.
Q. Okay. In your work for Gradient, have you found in the asbestos context a threshold below which you believe that there are no known adverse effects of exposure to asbestos?
MR. HUTCHINSON: Object to form.
Also, Counsel, that exceeds the scope of her report.
MR. ORENT: I understand. I'm getting into background and bias.
A. I'm sorry, can you repeat it?
BY MR. ORENT:
Q. Sure.
Do you believe that there's a threshold below which asbestos cannot cause human health problems?
MR. HUTCHINSON: Same objections.
A. I don't know. Again, I had a very

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small supporting role in the asbestos work here, so I'm not really prepared to discuss that.
BY MR. ORENT:
Q. Okay. So you started work on this on October 1st.
Between October 1st and October 9th, how many hours do you put in?
A. I have an invoice.
Q. I'd love to see that. That may be a good time for me to mark as Exhibit 2 to today's deposition a copy of the notice of deposition for today.
(Whereupon, Prueitt Exhibit Number 2, Notice of deposition, was marked for identification.)
A. Did you ask number of hours?
BY MR. ORENT:
Q. The number of hours, correct.
A. Myself through last Friday, this invoice indicates I worked 51 hours. And then because this invoice only goes through last Friday, also approximately 19 hours this week. However, other individuals have also worked on this with me.
Q. Okay. Can I take a look at that

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billing statement?
A. Sure (handing).
Q. So this runs through the 16th of October. How many hours were spent between the 10th and 16th of October?
MR. HUTCHINSON: Counsel, do you have another copy for the witness to look at?
MR. ORENT: I can hand this back. She just gave this this morning.
A. I am not sure. I cannot tell from this.
BY MR. ORENT:
Q. Between the 10th and the 16th, did you continue to do work reading materials and work on this case?
A. Yes, but very little. Actually it would have been -- it was probably around eight hours or so. Not very many.
Q. How about your staff, did they continue doing work on this?
A. Only helping me prepare for this deposition in terms of printing documents for me and organizing documents.
Q. Now, in terms of the report itself, did your staff do any of the work in terms of

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the substantive work of drafting the report, or did you draft all of it?
A. They did help in doing research to draft the report.
Q. And who -- let's start specifically.
What was your role in doing this report?
A. I made an outline as to what the report would contain, and I asked staff to help me go through some of the documentation and to summarize some of the documentation for me, and to help in the initial draft sections, some of them. And then I myself was responsible for the final report, or editing draft sections, and writing several of the sections.
Q. Were there notes exchanged between you and the members of your team on the various sections, or how was that work accomplished?
A. No. We met in person.
Q. Now, let me just look at this for a minute.
What role did Sara Pacheco Shubin -- P-A-C-H-E-C-O, next word S-H-U-B-I-N -- play in the work on this? Who is she?
A. She was the project manager for this

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work.
Q. What is a project manager?
A. At Gradient the project manager is responsible for kind of the day-to-day aspects of the project as far as helping find people to work on the project, dealing with getting the project started and in our accounting system, reviewing invoices before they go out.
Q. Are they responsible for any substantive work?
A. They can be. And in this case, yes, Sara was. She helped me to review a lot of the documents, a lot of the studies, and she helped in the early drafting of some of the sections.
Q. Now, in this particular case, you spent as of the 16th 51 hours. And based on your testimony that you spent about eight hours between the 10th and 16th, that leads me to believe that you spent about 43 hours and one-tenth, so 43.1 hours in the actual time period between when you got the assignment and drafted the report. Is that approximately correct?
A. Yes.
Q. Okay. Now, looking at your report,

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there's a number of reliance documents beginning on Page 18, and that continues between 18 and 23, and then there's a Section 6.2 which is sort of reliance documents in addition to the ones that were referenced in the report, and that goes to Page 24, 25, 26, and 27.

My first question to you is, in Section 6.1, References, prior to writing the report, did you yourself read each and every one of these references before you wrote the report?

A. Yes, at least portions of them.

Q. Did you read the entirety of each and every one of these references before writing your report?

A. No, because some of these are book chapters, and I only needed to look at certain sections of the chapter.

Q. Okay. So before writing your report, did you read the full Adami article?

A. No.

Q. Prior to writing your report, did you read the full Aigmueller article?

A. Yes.

Q. Did you read the AUGS Position Statement prior to drafting your report?

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A. Yes.

Q. Prior to drafting your report, did you read the AUGS Position Statement on Midurethral Slings? This is the second reference there.

A. Yes, I did.

Q. Did you read the AUA statement?

A. Yes.

Q. How about Barbolt, did you read that document in its entirety?

A. Yes, I did.

Q. And you read that before beginning work on this?

A. Yes, before drafting the report.

Q. And the second Barbolt, did you read that in its entirety before beginning work on this?

A. Yes, I did.

Q. Beck, did you read that in its entirety before beginning work?

A. No.

Q. What portions did you read -- did you read the entire section on Page 35 to 87?

A. No.

Q. And Eaton, did you read the entire section, Page 13 to 48, prior to beginning work

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on this?

A. No.

Q. Prior to drafting your opinions in this case, did you read the entire Ethicon Research Foundation 1971 document?

A. Yes.

Q. And did you read the entire 1972 document before beginning work?

A. Yes.

Q. Before beginning work, did you read the entire Ethicon Research Foundation 1975 document?

A. I don't remember.

Q. To date, have you read that entire document?

A. Yes.

Q. How about the Ethicon Research Foundation 1983, Prolene Sutures, did you read that in its entirety before beginning your report?

A. I don't think so.

Q. How about the next one, the 1983b?

A. I don't think so.

Q. How about the 1984, did you read that in its entirety before beginning your draft of

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your report?

A. I don't think so.

Q. How about the 1988 Prolene, did you read that in its entirety before beginning your draft report?

A. No.

Q. How about the 1989 Ethicon Research Foundation document, did you read that in its entirety before beginning your report?

A. No.

Q. How about the 1990a, did you read that in its entirety before beginning your report?

A. No.

Q. How about the 1990b?

A. No.

Q. 1990c?

A. No.

Q. How about the 1990d?

A. No.

Q. How about the 1991a?

A. No.

Q. 1991b?

A. No.

Q. How about the 1997 Biological Reactivity In Vitro Cytotoxicity-Elution Test,

did you read that in its entirety before beginning work on your report?
A. Yes.
Q. How about the 1997b?
A. Yes.
Q. How about the 1997c?
A. Yes.
Q. How about the 1964a, Study of Tissue Reaction to Colorless and Pigmented, Monofilament, Polypropylene Suture in the rat and the dog?
A. Yes.
Q. How about the 1964b?
A. No, not in its entirety.
Q. How about the 1965a?
A. No.
Q. How about the 1965b?
A. No.
Q. How about the 1973 Biological Evaluation in Rabbits?
A. No.
Q. How about the Ethicon 1991 Prolene Suture?
A. No.
Q. How about the 1996 Corporate Product

Characterization: Product Safety Profile - Prolene?
A. Yes.
Q. How about the TVT System 510(k) Notification, did you read that in its entirety?
A. Yes.
Q. How about the 28-Day Intramuscular Tissue Reaction Study in Rats?
A. Yes.
Q. And the 182-day Intramuscular Tissue Reaction Study?
A. Yes.
Q. You read that in its entirety?
A. Yes.
Q. And the 2001 study?
A. Yes.
Q. How about the Clinical Evaluation Report, the Ethicon 2013, did you read that in its entirety before starting your report?
A. Not in its entirety.
Q. And how about the European Commission 2013 Report?
A. Not in its entirety.
Q. How about Goutcher 1997, did you read that in its entirety?

A. Yes.
Q. How about Groutz, did you read that in its entirety prior to beginning your report?
A. Yes.
Q. How about Hazleton?
A. Yes.
Q. And Hill, did you reread that?
A. Yes.
Q. And the ISO Standardization, did you read that, the 2009a?
A. Not in its entirety.
Q. How about the 2009b?
A. Also not in its entirety.
Q. How about the IUGA 2014 Statement?
A. Yes.
Q. How about the Linder article?
A. Not in its entirety.
Q. How about Linkov?
A. Not in its entirety.
Q. How about Martini, 1993 internal memo?
A. Yes.
Q. How about the Nilsson article?
A. Yes.
Q. How about the NAMSA article?
A. Yes.

Q. And how about the 1997b NAMSA?
A. Yes.
Q. And 1997c?
A. Yes.
Q. And 1997d?
A. Yes.
Q. 1997e?
A. Yes.
Q. And 1997f?
A. Yes.
Q. And "g"?
A. Yes.
Q. How about "h"?
A. Yes.
Q. And the North American Science Associates 2015, did you read that in its entirety before beginning work on writing this report?
A. Yes.
Q. How about Olsson?
A. Yes.
Q. Rhomberg?
A. No.
Q. How about the Royal Australian and New Zealand College of Obstetricians and

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Gynecologists Position Statement?
A. Yes.
Q. How about Serati?
A. Yes.
Q. Svenningsen?
A. Yes.
Q. How about the EPA Region 3, is that just a reference you had on hand?
A. No, I actually looked at it.
Q. Okay. How about FDA 2013?
A. Not in its entirety.
Q. How about FDA 1995?
A. Yes.
Q. How about Wang?
A. Yes.
Q. How about Ward?
A. Not in its entirety.
Q. How about Weed?
A. Not in its entirety.
Q. Wickwire?
A. Not in its entirety.
Q. And Yoon?
A. Not in its entirety.
Q. Okay. Turning to 6.2, did you read all of the material in Section 6.2 of your

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report prior to beginning work on drafting your report in this case?
A. No.
Q. Do you agree with me that there's a significant portion of the documents in Section 6.2 that you did not read prior to completing your report?
MR. HUTCHINSON: Object to form.
A. No. There's very few that I didn't. Specifically I did not read the IARC -- on Page 27, the IARC Preamble, it's the first document listed on Page 27. I'm quite familiar with that document; however, I was not asked to evaluate carcinogenicity in this case, so I did not review that document.
BY MR. ORENT:
Q. Are there any other documents you did not read in their entirety before completing the draft report on October 9th?
A. I did not read also on the same page the MSDS materials, Sunoco MSDS in its entirety before drafting the report.
Q. Did you read it in partial?
A. Yes.
Q. Is there anything else in this

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Section 6.2 that you did not read in its entirety prior to writing your report?
A. I cannot answer that accurately, because some of the Eth.Mesh documents, I cannot tell what they are from here. However, I did at least open all of them, and if they looked relevant to what I needed to put in my report, then I would have read them, or at least skimmed them to see how relevant they were.
Q. Now, there's on here on 2014, 30(b)(6) Deposition Summary Exhibit. Was that a summary of the Barbolt deposition?
A. Sorry, what page?
Q. Page 25 under -- the first one under 2014.
A. I believe that's a list of studies.
Q. That's the exhibit that he used in his deposition, that he had brought to that deposition?
A. I believe so.
Q. So that's not a summary of his deposition that you were provided?
A. No.
Q. Were you provided any summaries of the material on either 6.1 or 6.2?

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A. Any summaries. No.
Q. Let me ask you, did you do your own research to identify each and every one of the sources cited in your report?
A. No.
Q. Were the references in Section 6.1 provided to you by Ethicon?
A. Some of them were.
Q. Which ones were not provided by Ethicon?
A. There are approximately 17 such references, because I thought we provided them, PDFs. I mean I could go through and try to remember.
Q. If you would.
A. So -- and they would only be in Section 6.1.
Q. Okay.
A. And that would be the Adami article, and then the Beck book chapter, the Eaton book chapter.
And then on Page 21, the European Commission 2013, the Hill 1965 article, the ISO 2009a and 2009b documents, the Linder article, the Linkov article, the Rhomberg article, US EPA

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Region 3 statement, the US FDA 2013, although I believe I later noticed that this document was in, but the initial -- when I read this initially, I had obtained this article myself.

Q. Okay.

A. The US FDA 1995 reference, the Ward article, the Weed article, the Wickwire article, and the Yoon article.

Q. Okay. In terms of the documents and articles listed in Section 6.2, was all of the material in Section 6.2 provided to you by counsel for Ethicon?

A. Yes, it was.

Q. Now, what particular searches did you use to identify the 17 articles that you yourself pulled? Why were these 17 articles the ones that you selected?

A. Right. They were mainly used to describe the methods that I used for my analysis, and these are very common references for these methods that others at Gradient have used as well.

Q. And there you're talking about weight of the evidence approach, is that correct?

A. And causation, yes.

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Q. So in terms of the substance of your report, the vast majority of the material that you were provided, if not all of it, serves as the basis of your opinions, is that right?

A. Yes, most of it.

Q. So there's very little original research that you utilized to form the opinions that have been presented in Sections 1 and 2 of your report?

MR. HUTCHINSON: Object to form.

BY MR. ORENT:

Q. And 3.

A. Well, I did perform literature searches to try to identify studies, toxicity of Prolene and polypropylene and TVT in the peer-reviewed literature. However, those searches didn't come up with anything.

Q. Approximately how long did you spend doing searches?

A. Our library staff helps with that, so that would be the work of Ruth Lyddy. Looks like she spent 12 hours.

Q. Do you know, in the 12 hours that Ruth spent, do you know what -- did she do a search of PubMed? Would that have been one of the

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sources?

A. Yes. PubMed. Actually I need to restate that.

It may not have been 12 hours on literature searches because she also did help catalog documents for us, so that's -- when we receive documents we catalog them so that we can find them easily again in the future, so she also did work on that. So that's likely not 12 full hours of literature searching.

However, back to your other question, in my report I note that the searches were in PubMed, and I believe Scopus, the Scopus database, but let me double-check that.

Yes, PubMed and Scopus database.

Q. What section are you on, 2 point --

A. 2.1, underneath the bullets.

Q. And those were the mesh terms that you used?

A. Yes.

Q. Okay. Now, if I understand your opinions in this case, your general opinion is that Prolene mesh in the TVT device is not cytotoxic. Does that summarize, adequately state your opinion?

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A. Almost.

Q. Okay. Why don't you state it.

A. That Prolene mesh in the TVT device is not cytotoxic in vivo, and that the weight of the evidence indicates that it is also not cytotoxic in humans.

Q. Would you agree with me that Prolene mesh is cytotoxic in vitro?

A. In some studies, but not all, yes.

Q. I'm going to shift gears as we start to get into some of the substantive stuff. We've been going about 50 minutes, 45 minutes, which is kind of early for our first break, but if you need it, I'm happy to go now. It's up to you?

MR. HUTCHINSON: Why don't we take five minutes.

THE VIDEOGRAPHER: Going off the record. The time is 10:34.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: Back on the record. The time is 10:43.

BY MR. ORENT:

Q. I just want to cover a few more preliminary things before we move forward.

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First of all, focusing on Exhibit 2, the notice of deposition that I've brought in front of you, did you bring -- I know that you brought with you a copy of your billing statement. Did you bring any other materials with you responsive to any of the items, Numbers 1 through 21 on Exhibit 2, Schedule A?

A. Well, I brought with me my report, this billing, and these binders which are the documents that I referenced in my report, so everything listed in Section 6.1.

Q. Okay. Now, as far as your binders are concerned, I see that there's some tabs on there. Are there any handwritten notes or highlights anywhere in your report, in the reliance material that you brought with you?

A. No. At least not by me. It is possible that -- actually, no. These were made from PDFs. I don't think so. I certainly didn't make notes.

Q. So that's a clean copy of the material listed on either Section 6.1 or 6.2 to your report, is that correct?

A. I guess it is possible a few of the documents may have had writing on them if they

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were hard copy before they were PDF'd, but again, those notes would not be made by me.

Q. Do you have handwritten notes on copies of articles somewhere?

A. No.

Q. What are the tabs that are -- the green stickies on the top there, the page flags?

A. Actually I don't know. I did not put those there. Let me see.

Q. I see actually there's a little note.

A. Okay. I don't know who did this. I think it's -- but this note looks like it's explaining, for example, this is a study, cytotoxicity study that covers both Elution and Agarose overlay, so I guess to help me identify.

Q. If you would identify just for the record --

A. What these are?

Q. Yes, what the pages are, and actually just read the note into the record. So identify, for example, tab, whatever the tab number is on your report, read in the note, and identify it's on the cover sheet of that report, so that there's a clear record at the end of this as to what exactly everything is that

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you're looking at.

A. Okay. And I apologize, I did not know these were here.

Q. That's fine.

A. I hadn't reviewed this, because I had already previously looked at most of these documents.

Okay. So in tab 19, the note says "both Elution and Agarose overlay studies reported."

And tab 20 says the same thing, "both Elution and Agarose overlay studies reported."

Tab 21, same note word-for-word.

Q. Just for clarification, tab 21, that's the 1990d Ethicon Research Foundation?

A. Tab 21?

Q. Yes.

A. It is the Goutcher 1997.

Q. So then what I'm going to do, those are not in the exact order, I'm going to keep having you do that, and what we'll do is take a copy of the index and put that as part of the record.

A. Okay. Tab 25, "both Elution and Agarose overlay studies reported."

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Tab 26, same note.

And tab 27, same note.

Q. Okay. And that index that you were referring to earlier, is that an index of all three binders that you brought with you?

A. Each binder has its own index.

Q. Okay. If you would just take a look at the other binders, and just verify for me that there's nothing else in there, tabbed or --

A. There's one on this second binder. Tab 36, the note says "Agarose overlay only."

And the third binder has no notes.

Q. Okay. So what I'd like to do now is mark the three cover sheets collectively as one exhibit. We can do that as Exhibit 3.

MR. ORENT: Actually I'm happy to do it that way if I get counsel's assurance that those documents are, in fact, what are on here, and that they're all in the production material, and there's no other notes.

MR. HUTCHINSON: We'll be happy to accommodate you, Counsel.

MR. ORENT: Okay. I don't think anyone needs additional copies of what we all already have five copies of.

(Whereupon, Prueitt Exhibit Number 3, Three index sheets from binders, was marked for identification.)

MR. ORENT: I'm going to go ahead and mark this as Exhibit 3.

And then as Exhibit 4, I'm going to just mark the billing statement that you provided us earlier this morning and we discussed.

(Whereupon, Prueitt Exhibit Number 4, Billing Statement, was marked for identification.)

BY MR. ORENT:

Q. Just do me a favor and hand me the notice of deposition. I'm going to try and keep everything here together for Maureen so we don't lose anything at the end of the day today. And keep your report in front of you.

Have you ever presented at DRI?

A. No.

Q. Do you know what DRI is?

A. Yes.

Q. What is DRI?

A. Defense Research Institute. I know they have occasional meetings.

(Whereupon, Prueitt Exhibit Number 5, Document titled DRI, Seminar, Toxic Torts and Environmental Law, was marked for identification.)

BY MR. ORENT:

Q. I'm going to mark Exhibit 5 a Seminar on Toxic Efforts and Environmental Law from DRI. And if you look at the list of sponsors on Page 8, you'll see Gradient listed there, is that correct?

A. Yes.

Q. And that's your company, is that correct?

A. Yes, it is.

Q. And if you look at -- if you look at the agenda on February -- excuse me, Page 2, February 28th through March 1st, there's a 6:00 p.m. networking reception sponsored by Gradient, correct?

A. Yes.

Q. That's your company, correct?

A. Yes.

Q. And at the 2:45 hour, David Dodge from Gradient presented, is that correct?

A. Yes.

Q. And he presented on a whole host of potential carcinogens, correct?

A. No, there are other chemicals besides carcinogens.

Q. And let me ask you this. If you turn to Page 4, it says "David Dodge is a board certified toxicologist with Gradient Corporation in Bend, Oregon, specializing in applied research, risk-based human health evaluations and risk communication. Mr. Dodge has characterized health risks from exposure to chemical and biological agents in products, workplaces and the environment. He has conducted detailed toxicological evaluations of various chemicals."

Did I read that correctly?

A. Yes.

Q. Do you know David?

A. Yes, I do.

Q. Have you worked with David?

A. Yes, I have.

Q. On what projects have you worked with David, what chemicals, generally speaking?

A. Generally, I have to think. I haven't worked with him for a while.

Q. Did you work with him on lead?

A. No.

Q. How about benzene?

A. No.

Q. TCE?

A. Yes.

Q. Parkinson's and formaldehyde?

A. No.

Q. Formaldehyde and leukemia?

A. No.

Q. Styrene?

A. No.

Q. Chloro --

A. Chlorpyrifos?

Q. Exactly.

A. No.

Q. And chromium?

A. No.

Q. If we were to read David's bio and substitute in your name, would it be accurate to describe you as a board certified toxicologist with Gradient Corporation, specializing in applied research, risk-based human health evaluations and risk communication?

MR. HUTCHINSON: Form.

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A. Yes, except for the word "Corporation." Our company is now only called Gradient. But the rest would be correct.
BY MR. ORENT:
Q. And would it similarly be accurate to say that Dr. Prueitt has characterized health risks from exposure to chemical and biological agents in products, workplaces and the environment?
A. Yes.
Q. And she has conducted detailed toxicological evaluations of various chemicals?
A. Yes.
Q. And we talked earlier, you did work for API?
A. Yes.
Q. That's the American Petroleum Institute, correct?
A. Yes.
Q. And one of the things that you've done with them is we talked about you looked at benzene, correct?
A. Not -- I don't believe that was for API.
Q. I'm sorry, for petroleum manufacturers

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you've looked at benzene, correct?
A. I've done very little benzene work, and I actually can't remember specifically who it was for.
Q. Regardless, you've done work for API, the American Petroleum Institute, correct?
A. Yes, I have.
Q. And you've written policy papers for them, correct?
A. Policy papers? I have written comments to regulatory agencies for them, and I have written peer-reviewed manuscripts and letters to the editor for them.
Q. I'm going to hand you what's been marked as Exhibit 6 to today's deposition.
(Whereupon, Prueitt Exhibit Number 6, Document titled Comments on US EPA's Proposed Reconsideration of the 2008 NAAQS for Ozone dated 2/2/09, was marked for identification.)
BY MR. ORENT:
Q. And in this particular piece that I've handed you, Gradient was retained to oppose lowering the standard that EPA utilized for ozone, is that correct?

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A. Yes.
Q. And what you argued here is essentially that there is no evidence of ozone exposure and adverse human health effects below the .08 parts per million, is that right?
A. Yes.
Q. And what ultimately happened with EPA's rulemaking on this?
A. They just lowered the standard within the last week or two.
Q. Thank you. You can put that down.
And you talked earlier that you'd worked with Barbara Beck with lead, correct?
A. Yes.
MR. ORENT: Mark as Exhibit 7.
(Whereupon, Prueitt Exhibit Number 7, Document titled Gradient to Participate in DRI Tox Torts and Environmental Law Seminar Feb 9-10 in Miami Beach, Florida, was marked for identification.)
BY MR. ORENT:
Q. Did you assist Barbara Beck in preparing for this DRI presentation in 2007?
A. No.

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Q. Have you assisted in the preparation of other DRI presentations for Barbara or anyone else?
A. No, I have not.
Q. Did I ask you about Julie Goodman?
A. No.
Q. Do you know Julie Goodman?
A. Yes, I do.
Q. Have you worked with Julie Goodman?
A. Yes.
Q. How frequently?
A. Quite frequently.
Q. And have you worked with her on asbestos?
A. I don't think so.
Q. Do you disagree with her opinions?
A. I don't know her specific opinions.
Q. I'm going to hand you what's been marked as Exhibit 8 in this deposition.
(Whereupon, Prueitt Exhibit Number 8, Document titled Defending the Wire and Cable Asbestos Cases, was marked for identification.)
BY MR. ORENT:
Q. Have you worked with Julie in

litigation before?
A. Yes.
Q. And were you aware that Julie helped prepare this presentation on Defending the Wire and Cable Asbestos Cases?
A. No, I was not aware of this.
Q. All right. You can put that aside.
(Whereupon, Prueitt Exhibit Number 9, Robyn Prueitt, Ph.D, DABT biography, was marked for identification.)
BY MR. ORENT:
Q. I'm going to hand you what's been marked as Exhibit 9. "Representative Projects." First, "Carcinogenic Assessment: Evaluated whether the weight of epidemiology, animal toxicity, mechanistic, and pharmacokinetic evidence indicates that toluene diisocyanate" --
A. Diisocyanate.
Q. -- "diisocyanate is a human carcinogen. This analysis used Gradient's hypothesis-based weight of the evidence approach and was published in peer-reviewed journal."
What was your conclusion?
A. That toluene diisocyanate is not likely to be a human carcinogen.

Q. Okay. And there's a wide body of literature that supports the notion that toluene is, in fact, a human carcinogen, is that correct?
MR. HUTCHINSON: Object to form.
A. No.
BY MR. ORENT:
Q. Are there papers -- are there authors that would disagree with you?
A. I'm not sure.
Q. "Review of Toxicogenomics: Critically reviewed global gene expression profiling data for a population exposed to benzene and determined whether the expression profile could be used as a biomarker of benzene toxicity in a broader population, particularly without proof of benzene exposure from a specific source."
What were your conclusions in that project?
A. That project I was just reviewing a published article on gene expression profiling, and so the conclusions were along the lines of, you know, whether the science is strong enough to say that a gene expression profile can indicate benzene toxicity in people, even if

there's no proof that they were exposed. So it was more just critically reviewing a manuscript.
Q. And what were your conclusions?
A. That the state of the science is not such that one can use a gene expression profile to conclusively determine whether benzene has caused toxicity.
Q. In other words, you can't use the gene's expression to determine whether or not someone has had benzene exposure?
A. No, it was you cannot use it to determine whether someone has suffered adverse effects of benzene.
Q. Do you believe that there is a biomarker of benzene exposure, based on your work?
A. I'm not sure.
Q. Do you believe -- next is the lung cancer from exposure to asbestos during vehicle brake repair.
Did you reach any conclusions with regard to that project?
A. I don't remember. I think I had an extremely small role on that project.
Q. You were retained by asbestos brake

manufacturers in that project, correct?
A. Someone at Gradient was, I assume.
Q. And ultimately, the conclusion there was that the asbestos from brakes was not a source or contributor to the cancer, correct?
A. I don't recall.
Q. The next one, "Weight-of-Evidence Analysis: Used Gradient's hypothesis-based weight-of-evidence approach to assess whether epidemiology, toxicology, and mechanistic evidence supports chlorpyr" --
A. Chlorpyrifos.
Q. Thank you.
-- "being a neurobehavioral toxicant in humans at relatively low exposure levels."
And what were the conclusions there?
A. That the evidence indicates that chlorpyrifos is not a neurobehavioral toxicant at the low exposure levels that humans are exposed to.
Q. "Bioavailability Assessment: Assessed whether animal, mechanistic, and epidemiological data are consistent with the nickel ion bioavailable model, which asserts that the carcinogenicity of nickel-containing substances

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is based on the bioavailability of the nickel ion at nuclear sites of target respiratory epithelial cells."

And what conclusions did you reach there?

A. That different forms of nickel have different bioavailability in the body, and so the conclusions were that the data regarding bioavailability do not support that certain forms of nickel are carcinogenic.

Q. So in other words, the conclusion there was certain kinds of nickel can't cause cancer?

A. Did you say can or can't?

Q. Cannot.

A. Yes.

Q. "Toxicity Summary: Classified, summarized, and entered relevant studies of lead and bisphenol A into IUCLID database, a database for the intrinsic and hazard properties of chemical substances that companies can use to submit data under the Registration, Evaluation, Authorization, and Restrictions of Chemical legislation in Europe."

What was the project there?

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A. So those were two completely separate projects with separate clients, one for lead, one for bisphenol A, and that is -- and these projects involved reviewing and writing short summaries of a large number of toxicology studies of either lead or bisphenol A, and then entering those summaries into a database that is part of chemical regulation in Europe.

Q. And did you reach any conclusions with lead?

A. No. Both of these studies were not to reach conclusions, they were simply to summarize the literature that is out there, but not to synthesize it and come to any conclusions about it.

Q. Okay. So going back to what your core opinions in this case are, I understand that it is that TVT mesh is not cytotoxic in vivo, and that the weight of the evidence, according to you, is that it is not cytotoxic in humans, is that correct?

A. Yes.

Q. And you said there is evidence of cytotoxicity in vitro, correct?

MR. HUTCHINSON: Object to form.

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A. There is some evidence of potential cytotoxicity in vitro.

BY MR. ORENT:

Q. Now, in terms of your final opinion, which is the weight-of-evidence, is that TVT is not cytotoxic in humans. Does that rely upon the foundation of human clinical evidence?

A. In part, yes.

Q. Does it rely on your review of in vivo cytotoxicity studies?

A. In part, yes.

Q. And does it rely upon your evaluation of in vitro studies?

A. In part, yes.

Q. Is there anything else that it relies upon?

A. The position statements from different medical societies.

Q. Anything else?

A. Just general toxicology principles.

Q. Okay. Anything else?

A. I don't think so.

Q. Okay. Now, Gradient, this is a lab, right?

A. Gradient?

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Q. Yes.

A. No.

Q. Do they have lab facilities?

A. No, we don't.

Q. Do you have, if a project calls for it, the ability to do your own testing?

A. No. We would have to find a contract lab to do the testing.

Q. And did you inquire about doing any of your own cytotoxicity testing?

A. No.

Q. How about any of your own in vitro testing?

A. No.

Q. So I want to start with where you began in your report on your evaluation of the in vivo studies. And I think it may be easier here, we're going to switch between sections, and really to switch and go right back to data Table A.1.

If we look at A.1, first of all, did you review each and every one of the cytotoxicity studies cited in Table A.1?

A. Yes.

Q. Did you personally review them all

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before completing this data table?
A. Probably not in their entirety, but yes.
Q. How about Table A.2, In Vitro Cytotoxicity - the Agarose Overlay. Did you read all of those before creating that data table?
A. Before or during, yes.
Q. Now, would you agree with me that the first study in A.1, Study ID M83-184, that is not a -- that is not a -- strike that.
That's a suture study, correct?
A. Yes.
Q. That did not involve the same mesh used in TVT, correct?
A. No, it is the same Prolene mesh that is used in TVT; however, it was not taken from a TVT device.
Q. Well, I guess that's my question. Was it taken from a sheet of Prolene, or was it a Prolene suture?
A. It was a Prolene suture.
Q. Okay. So I want to be very specific with the terms. When I'm going to say mesh, I'm going to refer to the sheet of mesh, or I'll try

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and be clear.
But this whole study that concluded that it was not cytotoxic, had no cytotoxicity, that was a suture study, correct?
A. Yes.
Q. The next one dated 8/22/1988, that also is a suture study, correct?
A. Yes.
Q. The next one, 6/12/1997, that is a -- actually that's a polypropylene mesh, correct?
A. Yes.
Q. That's not Prolene, correct?
A. I'm not sure. I would have to double-check the study.
Q. Well, for example, if you look later on --
A. Actually it should be, because it's testing different portions of the device such as the needle, the heat-shrink tubing, the sheath, so actually I do believe the mesh is Prolene, it just states polypropylene in this table.
Q. Okay. That's different -- and that's a different way of stating it than you typically state it here; normally you deviate between PP and Prolene, correct?

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A. Yes.
Q. At least that's how I've read your data table.
A. Yes.
Q. And this particular study found marked cytotoxicity with the polypropylene portion of the Prolene mesh, correct?
MR. HUTCHINSON: Object to form.
A. With the mesh, yes, but that is Prolene mesh.
BY MR. ORENT:
Q. And found marked cytotoxicity, correct?
A. Yes.
Q. The next one is the Sterile Ulmsten device. And do you know what the difference between the Ulmsten device is and the TVT?
A. Yes, I believe they are the same thing.
Q. Do you know, do they use the exact same Prolene mesh at the time it was still called the Ulmsten device, as opposed to when it later became the TVT?
A. I'm not sure.
Q. Did you investigate that to determine

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whether or not it was the same mesh that was marketed in the United States?
A. I think I did, but I can't remember.
Q. Now, the next one is the Sterile Ulmsten device, correct?
A. Yes.
Q. And the mesh there was found by Dr. Barbolt to be severity cytotoxic, correct?
A. Yes.
Q. And the next two, the NAMSA studies, 1987a and "b", those used raw polypropylene meshes, but those are not -- those are not Prolene, correct?
MR. HUTCHINSON: I'm sorry, Counsel, can you tell me where you are?
MR. ORENT: Sure, 7/29/97, raw polypropylene mesh, noncytotoxic, NAMSA 1997a.
A. No, they are Prolene mesh.
BY MR. ORENT:
Q. They are.
Okay. And the next one, sterile polypropylene mesh of TVT device, that found moderate cytotoxicity, correct?
A. Yes.
Q. And then the next one, polypropylene

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mesh from TVT device made with low temperature HST, severe cytotoxicity, correct?
A. Yes.
Q. Polypropylene from the finished TVT device, slight cytotoxicity, correct?
A. Yes.
Q. And then it went on to find ELTDP noncytotoxic, Santonox R, severe cytotoxic, and Procol LA-10, severe cytotoxicity, is that correct?
MR. HUTCHINSON: Object to form.
A. Yes, although the severe cytotoxicity for Santonox R was only at the higher concentration of 3 milligrams per milliliter, but not at the lower concentration of 0.2 milligrams per milliliter.
BY MR. ORENT:
Q. Now, at the bottom there's a "d" and an "e", and those refer back up to the top to the PSE Accession No. 97-0174 and PSE Accession No. 97-0128, and those say that the documents were unavailable.
A. Right.
Q. So does that mean you didn't have these studies available to you when you drafted

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this report?
A. It means I did not have the study reports; however, I had other documentation about the results.
Q. So just to be clear, you didn't have the raw data for "d" and "e", correct?
A. Correct.
Q. And for "c", which would be Accession No. -- I must be missing it?
A. It's in the Conclusion column.
Q. Oh, there. "PE sheath - Noncytotoxic," it says "Discrepancy between references."
What does that mean?
A. That means that in one reference it labeled the result as noncytotoxic, but I think somewhere else it may have labeled the result as slight cytotoxicity, which still indicates that it's not cytotoxic.
Q. Now, for each of these studies that you rely on in this table, did you go through and re-review the raw data in forming your conclusions?
A. Yes.
Q. And on any of these, do your

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conclusions differ in any way between what the author found and what you've read here?
A. No.
Q. Did you look at the original photomicrographs of the explanted material -- excuse me, any of the photomicrographs of any of the tests, the elution studies, to determine and verify the written findings?
MR. HUTCHINSON: Object to form.
A. No.
BY MR. ORENT:
Q. Table A.2. You'd agree, again, that there are tests here that show that there's marked cytotoxicity with regard to the mesh?
MR. HUTCHINSON: Object to form.
A. Yes, one study does note marked cytotoxicity.
BY MR. ORENT:
Q. Okay. And again, you note with a "c" that at least one of these studies was not available to you, and you're relying upon some other document to form the basis of your opinion, is that right?
A. Yes.
Q. As you sit here today, can you tell me

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what specific document you rely on for that opinion here?
A. It would be the -- so this would be for the study PSE Accession No. 97-0128, and so in the Reference column for that study, because I did not have the raw data, the references listed in that column would be those that I relied on for the results of this study.
Q. Okay. If we go to the Implantation Studies next, I'm just going to go in order, 3/10/64, those are sutures, correct?
A. Yes.
Q. They're not Prolene, correct?
A. Correct.
Q. 7/25/64, sutures, polypropylene, but not Prolene, correct?
A. Correct. Well, the study report does not refer to them as Prolene, it only refers to them as polypropylene.
Q. Is it fair to say that when you say something is Prolene it is actually Prolene? For example, beginning on 5/20/71, it says "Prolene suture," and any reference that just say "PP suture" just mean polypropylene suture?
A. Yes. For the sutures, yes, that's

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correct.
Q. And would you agree with me that all of the studies listed on Page 3 are suture studies?
A. Yes.
Q. Would you agree with me that all of the studies cited on Page 4 are suture studies?
A. Yes.
Q. Okay. The top one on Page 5, that's a suture study as well?
A. Yes.
Q. Okay. The next study is a 10/21/1973 study of Prolene mesh and Marlex mesh, correct?
A. Yes.
Q. Are all -- in your opinion, are all polypropylenes the same?
A. Polypropylene is polypropylene. But I would not say all polypropylene meshes are the same.
Q. In terms of the cytotoxicity, are all polypropylenes the same?
MR. HUTCHINSON: Object to form.
A. I don't know. I didn't look at different -- at a large number of polypropylene products.

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BY MR. ORENT:
Q. Well, this one is a 1973, it looks at Prolene mesh and Marlex mesh, correct?
A. Yes.
Q. And do you believe that the results for Prolene and the results for Marlex can be -- that in terms of evaluation of the data you can draw common inferences from the findings? You treat them as the same for purposes of reviewing this study?
MR. HUTCHINSON: Form.
A. No.
BY MR. ORENT:
Q. The next one is 6/16/1999, it's a rat study, and the TVT mesh itself found a minimal to moderate cytotoxic reaction, is that correct?
A. Only at seven days after implantation, yes.
Q. Okay. And then minimal to mild?
A. At 14 days, yes.
Q. At 14 days.
And then a mild cytotoxic reaction at 28 days, correct?
A. Yes.
Q. Polypropylene showed minimal to

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moderate at seven days, correct?
A. Yes.
Q. Minimal to mild at 14 days?
A. Yes.
Q. Mild at 28 days?
A. Yes.
Q. And that's a rat, correct?
A. Rat study, yes.
Q. PSE Accession 99-0115 dated 4/6/2000, that's a rat study, correct?
A. Yes, it is.
Q. And polypropylene mesh and polypropylene mesh with triclosan, was a gluteal muscle study, and it found a minimal to moderate reaction, correct?
A. Yes. Although that should say Prolene mesh. Both the mesh and the mesh with triclosan were Prolene.
Q. Okay. And the polypropylene, a subcutaneous rat test found that there was a minimal to mild response in rats on 7/12/2001, is that right?
A. Yes, with Prolene mesh.
Q. Then we look at Prolene mesh in 2002, and there was a mild to moderate response at

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seven days, minimal to moderate at 14 days, mild to moderate at 28 days, and minimal to moderate at 14 and 28 days, is that right?
A. Yes.
Q. And then subcutaneously we see minimal to moderate at seven days, minimal to mild at seven days, minimal to mild at 14 days, minimal to moderate at 28 days, and minimal to mild at 28 days, is that right?
A. Yes.
Q. Now, all these studies are rat studies, correct?
A. Which studies?
Q. I'm sorry. The ones that actually -- focusing on Page 5 and 6, actually they either involve rats or rabbits, correct?
A. The studies with mesh, yes.
Q. Okay. And in making your decision on -- on forming your opinions on cytotoxicity, you actually only looked at five studies involving mesh, correct?
MR. HUTCHINSON: Object to form. Mischaracterizes the testimony.
A. I only looked at, yes, five in vivo studies in animals of the Prolene mesh, yes.

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BY MR. ORENT:
Q. And on those particular studies -- well, first of all, did you do anything to verify that Ethicon had given you every single in vivo study that it had in its possession?
A. No, I didn't.
Q. Do you know, for example, whether or not Ethicon had dog studies available to it with the actual Prolene mesh?
A. No, I don't.
Q. Do you know whether it had sheep studies available to it with the actual Prolene mesh?
A. No.
Q. Would you have wanted to see any dog studies related to the Prolene mesh?
A. It would depend on what type of study it was.
Q. If we're talking in vivo studies, implantation studies?
A. In vivo implantation study, if it evaluated endpoints that could inform whether it was cytotoxic, yes.
Q. And would the same be true for sheep studies?

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A. Yes.
Q. Now, as you sit here today, do you have an opinion as to what type of cytotoxic information can be gleaned in the quality of information between a rat study and a dog study?
A. Can you repeat that?
Q. Sure.
As you sit here today, do you have -- in your professional knowledge, education and training, are you able to quantify or qualify the differences between a dog study and a rat study in terms of the ingrowth, the types of collagen, and the comparability to humans between the different animal species?
MR. HUTCHINSON: Object to form.
A. No.
BY MR. ORENT:
Q. So as you sit here, Doctor, are you able to inform us as to how a rabbit, the tissue ingrowth and the macrophages and the whole process that's being observed in vivo, how the cellular structures compare to those of a human?
MR. HUTCHINSON: Same objection.
A. No.
BY MR. ORENT:

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Q. As you sit here today, are you able to tell the jury exactly how one can compare a rabbit study to what might be anticipated in a human being, based on the various structures that you could see under a microscope?
MR. HUTCHINSON: Same objection.
A. No.
BY MR. ORENT:
Q. Same question with a dog, as you sit here today, in terms of the physical features that can be observed in an in vivo study under a microscope after a material is explanted, are you able to tell us how that would be anticipated to correlate with a human being?
MR. HUTCHINSON: Same objection.
A. No. I'm not a pathologist, so no.
BY MR. ORENT:
Q. Okay. And are you able to describe how the collagen is different between a dog and a human?
A. No.
Q. How about the scarification, are you able to determine how the scarification in a rat is different than the scarification in a human?
A. No.

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Q. Are you able to determine how the scarification in a dog is different than in a human?
A. No.
Q. Do you know what reactive oxygenated species are, or ROS?
A. In general, yes.
Q. Do you know the difference in the release of ROS in a rat versus that of a human?
A. No.
Q. Okay. Do you have an understanding as to the difference between the release of ROS from a dog and a human?
A. No.
Q. How about a sheep and a human?
A. No.
Q. Do you have an understanding as to whether or not the quadriped nature of a rabbit makes any difference in evaluating the cytotoxicity at the site-specific locations that were done in these studies and what might be inferred from the human pelvis of a woman?
A. No.
Q. Do you have any understanding, as you sit here today, how the quadriped nature of a

dog might impact the cytotoxicity in the locations implanted in these studies between that and the human pelvis?

A. No.

Q. As you sit here today, do you have any understanding as to how the quadriped nature of a rat would differ with the production of ROS and that in the human pelvis?

MR. HUTCHINSON: Object to form.

A. No.

BY MR. ORENT:

Q. In terms of physical structure and cytotoxicity, do you know how a skin test in a rat compares with results in a human pelvis?

A. No.

Q. Do you know how a skin test or under-skin test of a dog would compare with the human pelvis of a woman?

A. No.

Q. Do you know how the human pelvis of a woman would compare to a skin test on a sheep?

A. No.

Q. Okay. How about a pelvis-to-pelvis comparison, do you know how a pelvis test, the structural test of reactivity in a rat's pelvis

would compare to that of a human's pelvis?

A. No.

Q. How about with regard to a dog, do you know how a dog's pelvis and the implantation in a dog's pelvis of a piece of mesh would compare in terms of the reaction to that in the human pelvis?

MR. HUTCHINSON: Form.

A. No.

BY MR. ORENT:

Q. And a sheep's pelvis, do you know how that would react between the implantation in a human's pelvis and -- excuse me, between the implantation of mesh in a sheep's pelvis and that in a human's pelvis, do you know how one would be able to correlate that reaction?

MR. HUTCHINSON: Form.

A. No.

BY MR. ORENT:

Q. Now, Doctor, in terms of predictability of in vivo studies, did you do any research to determine which animals would be the most appropriate to draw inferences from an in vivo specimen to a human subject?

A. No.

Q. Are you aware that the -- do you know who IUGA is?

A. Yes.

Q. IUGA is International Urogynecological Association, correct?

A. Yes.

Q. And are you aware that they have had roundtables?

A. No.

Q. Doctor, were you provided any information that suggests that the IUGA roundtable evaluated the data and made determinations as to the suitability of particular animals for in vivo testing?

MR. HUTCHINSON: Object to form.

A. No.

BY MR. ORENT:

Q. Were you aware that the IUGA recommended one specific type of animal for in vivo testing?

A. No.

Q. Doctor, would that have been information that you would have wanted to see in forming your opinions in this case?

A. It would have been helpful.

Q. Okay.

A. But I don't know that it would have changed my conclusions.

Q. Now, Doctor, what we talked about so far was the in vitro studies. In your report, if you go to Page 10, you make the statement "Ethicon has extensively investigated the safety of Prolene sutures and mesh, and the relevant cytotoxicity and the implantation studies are evaluated below."

Doctor, what basis do you have to support the conclusion that Ethicon has extensively investigated the safety of Prolene sutures and mesh?

A. All of the studies in my tables.

Q. And what have you used as your comparator? So if that, for example, is extensive, how many other companies have you looked at to -- or what other comparison data did you look at to determine that that was extensive versus the alternative?

A. I didn't do a comparative analysis.

Q. Okay. So what basis do you have to say, other than saying that there's a number that's on that data table, whatever that is, 19

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studies, what basis do you have for saying that that is extensive?
A. Just I would say the number of studies and the -- some of the documents from Dr. Barbolt, he did a risk assessment and cytotoxicity evaluations to show that Ethicon was definitely interested in understanding the safety of this material.
Q. But we talked earlier that there were only five studies related to mesh, is that right?
A. Five in vivo studies of Prolene mesh that I evaluated, yes.
Q. Okay. Would you agree with me that you could not say Ethicon has extensively investigated Prolene mesh in vivo?
MR. HUTCHINSON: Objection. Asked and answered.
A. I would not -- sorry, can you ask that again?
BY MR. ORENT:
Q. Could I take and -- just take that statement that you have and just alter it a little bit to say Ethicon has extensively investigated the safety of Prolene mesh in vivo,

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as you sit here today, could you offer to a reasonable degree of scientific certainty that opinion?
MR. HUTCHINSON: Object to form.
A. That they have extensively investigated it, yes, in vivo.
BY MR. ORENT:
Q. So five studies is sufficient for you to call something extensive, is that correct?
A. In the context of all the other data available, yes.
Q. Five studies, correct?
MR. HUTCHINSON: Objection. Asked and answered, Counsel. Move on.
BY MR. ORENT:
Q. Now, with regard to these studies, again, you have no comparator, correct?
A. Right.
Q. And have you ever worked with a company developing an implant to determine how many studies need to be done in vivo in order to reach a significant endpoint?
A. No.
Q. Do you have any basis to say, as you sit here today, from your experience, to say

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that five in vivo studies involving Prolene mesh meets industry standards?
MR. HUTCHINSON: Object to form.
A. I don't know the industry standards.
BY MR. ORENT:
Q. Okay. So wouldn't it be true that you really can't say, compared to what everybody else in the industry is doing, you cannot say that what Ethicon did here was extensive. Would you agree with that?
MR. HUTCHINSON: Form.
A. My statement wasn't really comparing to the industry. It was just indicating that the total of the data, not just the in vivo studies, but the in vitro and the human clinical studies are together extensive.
BY MR. ORENT:
Q. Now, if hypothetically another company, let's say AMS, performed 50 in vivo studies prior to putting their product on the market, you would then not be able to say that Ethicon's five would be significant, or extensive, correct?
MR. HUTCHINSON: Form.
A. Not comparative to that, no.

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BY MR. ORENT:
Q. Okay. Now, you read Dr. Barbolt's deposition, correct?
A. Most of it.
Q. And in your report, on Page 11, you state that the findings, and this is right above the 3.2 -- 3.1.2 area, you discuss Santonox R and Procol LA from Barbolt?
A. Yes.
Q. And you call them surfactants?
A. Surfactants.
Q. Surfactants. Okay.
Now, do you know -- would you agree with me that the longer Procol LA is in the human body in a piece of mesh, the more likely it is to migrate?
A. I don't know.
MR. HUTCHINSON: Form.
BY MR. ORENT:
Q. Would you agree that Procol LA blooms to the surface?
A. I have read that. Upon heating at high tem -- or heating the mesh, yes.
Q. Do you know whether or not Procol LA blooms to the surface in the presence of

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reactive oxygenated species?
A. I do not know that.
Q. Do you know whether or not there are other factors in the in vivo environment or the in vitro environment which can cause Procol LA to bloom to the surface?
A. No, I don't know.
Q. Would it be fair to say to a reasonable degree of professional certainty you do not know of the other factors beyond heating that affect Procol LA?
A. That affect its blooming to the surface?
Q. Correct.
A. Correct.
Q. And likewise, beyond heating, you do not have any information as to what promotes Procol LA's migration away from the mesh into other cells except for heating, correct?
MR. HUTCHINSON: Object to form.
A. Correct, that's not within my area of expertise.
BY MR. ORENT:
Q. Okay. And your understanding about Procol LA is entirely taken from Dr. Barbolt's

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work, is that correct? Let me rephrase that.
Your understanding of Procol LA and its reactivity to heat is entirely based upon Dr. Barbolt's deposition, is that correct?
A. No. There were other documents where I saw discussion of the potential for Procol LA-10 to bloom to the surface.
Q. Okay. Those were internal corporate documents, correct?
A. I can't remember if they all were. It's possible.
Q. Did you do a thorough comprehensive literature review of Procol LA prior to writing your report?
A. One of my staff did some searching of Procol LA-10, and I don't believe he came up with anything in the peer-reviewed literature.
Q. Did you develop, or did you -- would you agree that you're not an expert on Procol LA-10?
A. Yes.
Q. Now, when you say "with evidence indicating that the positive results are likely attributable to the surfactant additive Procol LA which migrates to the surface of the mesh

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when it is heated at sterilized temperatures," you don't know, again, what other factors attribute to Procol LA's migration to the surface, correct?
A. Correct.
Q. You don't know what other factors might lead Procol LA to migrate into other tissue in the human body, correct?
A. Correct.
Q. Do you know what the LD50 is of Procol LA?
A. No, I don't.
Q. And just for the record, what's an LD50?
A. It's the dose of a chemical at which 50 percent of the animals exposed at that dose will die.
Q. And do you know whether or not there's a dose-response curve that's been developed for Procol LA?
A. I don't know.
Q. Those are two areas, LD50 and dose-response, that are typically in the realm of a toxicologist, correct?
A. Yes.

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Q. You say "While this additive was cytotoxic when it was applied directly to cultured cells, this does not replicate the conditions of TVT exposure in vivo; these results must be considered in relation to other data available when evaluating the potential cytotoxicity of the tested materials."
Do you know, percentage-wise, on a percentage basis, over a ten-year period what percentage of the Procol LA that's in a piece of mesh originally will actually bloom to the surface and migrate?
A. No, I don't.
Q. So would you agree with me that you can't actually say that the culture cells won't get the same dose ultimately as the cells next to mesh over a ten-year period --
MR. HUTCHINSON: Object to form.
BY MR. ORENT:
Q. -- from Procol LA?
A. It's not likely that they will, because in vitro it's naked cells in a petri dish being exposed directly to this chemical, whereas in the body the mesh is on cells, but there, you know, is a circulatory system,

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there's many other things going on in vivo that the in vitro tests cannot replicate. So the dose of the Procol LA-10 is not comparable in vitro to in vivo.

Q. Okay. Now, in terms of the actual amount released, I should talk in terms of release, as you sit here today, you cannot say that the amount of Procol LA released from mesh into the human body over a ten-year period is not the same quantity as that which was tested in the in vivo dish -- in vitro dish, correct?

MR. HUTCHINSON: Form.

A. I cannot say that, but I believe many -- several different concentrations were tested in vitro, but I do not know how they compare to the in vivo situation.

BY MR. ORENT:

Q. Okay. Now, we next talked about the in vivo studies that involved both mesh and non-mesh. In terms of the endpoints, was necrosis the only endpoint that you were looking for in terms of determining whether or not something was cytotoxic or not?

A. No. It was the primary endpoint for cytotoxicity, but I also know that wound healing

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is -- or delayed wound healing can be an indication of cytotoxicity. So I was looking at the general tissue response, specifically necrosis, fibrosis, myofiber regeneration, and inflammation, but with necrosis being the most likely indicator of cytotoxicity.

Q. Did you look for whether or not foreign body giant cells were present?

A. No.

Q. How about macrophages?

A. No.

Q. How about any cells indicating an acute foreign body reaction?

A. No, just general inflammation.

Q. How about scarification?

A. Yes, the fibrosis.

Q. Did you look at whether or not bridging fibrosis existed in each of these studies?

A. Not specifically.

Q. Do you know what bridging fibrosis is?

A. No.

Q. Okay. Do you know how dense the collagen was in areas where there was reported to be little cytotoxicity? In other words, if

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we're using scarification as a metric in these animal studies, focusing on the mesh five, what layer of scarification, what amount of scarification would be the difference between minimal and mild?

MR. HUTCHINSON: Object to form.

A. I don't remember. I would have to look that up.

BY MR. ORENT:

Q. Okay. Did you do an independent evaluation of each of the specimens and each of the findings to determine whether or not in terms of scarification it was consistent with what your own definition of, for example, extensive scarification might be, or minimal scarification, or something like that?

MR. HUTCHINSON: Form.

A. No. I'm not a pathologist, so I had to rely on the study authors.

BY MR. ORENT:

Q. Okay. So you relied, for each of those five studies, you relied upon the findings of the authors, correct?

A. Yes.

Q. And you yourself would not be

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qualified to do an in vivo study, correct?

A. No.

Q. And, in fact, that would go towards either a pathologist or a combination of physician and pathologist, correct?

A. At least a pathologist.

Q. Okay. And you can only go on the pathology reports that are provided to you about whether or not there's evidence of a particular finding or not, correct?

A. Correct.

Q. And so if something was not an endpoint that was specifically evaluated for, you couldn't say whether or not it was there or not there, you could only state something like there's no evidence presented of X, correct?

MR. HUTCHINSON: Object to form.

A. Well, these studies are supposed to look at several different things. And so, for example, these studies are supposed to look for necrosis. So if necrosis is not mentioned, I mean if the study has been done well, then that means that necrosis is not present.

BY MR. ORENT:

Q. Okay. Now, chronic inflammation, what

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is the marker that you use for the definition of chronic inflammation when reviewing these studies? Do you look at it in terms of the presence of foreign body giant cells?
A. No.
Q. Okay. Do you look at it in terms of the presence of bridging fibrosis?
A. No. I look at it as the interpretation of the study authors to whether they saw chronic inflammation.
Q. Okay. So this is -- when you write these paragraphs on Page 12 and 13, those are more or less summaries of the information that the study authors themselves presented, correct?
A. Correct.
Q. Okay. That's not your own independent evaluation of those particular studies, correct?
MR. HUTCHINSON: Object to form.
A. As far as looking at the pathology, correct.
BY MR. ORENT:
Q. Okay. And you're not reaching independent conclusions from what the authors reached in their findings, correct?
A. No, not from the pathology, no.

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Q. You're summarizing the findings of the original authors?
A. Yes.
Q. Okay. The next thing that you do is a summary of the clinical evidence. You "did not identify any clinical studies in which cytotoxicity of TVT was the primary endpoint. However, multiple clinical studies show no evidence of cytotoxicity in women who have been surgically implanted with TVT."
Did you do a comprehensive review of the literature regarding TVT?
A. Not myself, no.
Q. Did your team do a comprehensive literature review of the peer-reviewed medical literature on TVT?
A. We didn't -- well, it depends on what you mean by "comprehensive." But no, I did not do literature searches to identify all of the studies.
Q. Okay. For example, when I think of comprehensive literature review, I think of reviewing all of the case studies out there, all of the series, case series, all of the retrospective studies, all of the prospective

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studies, and randomized controlled trials.
Would you agree that that makes up the comprehensive universe of what literature would look like, could look like?
MR. HUTCHINSON: Object to form.
A. Yes.
BY MR. ORENT:
Q. And so in terms of case studies, did you direct anyone on your team to perform a comprehensive search for all of the human case studies on TVT?
A. No.
Q. In terms of the work that you did, did you direct anyone on your staff to do a comprehensive search for all of the case series studies with TVT?
A. No.
Q. With regard to the work that you did, did you direct anybody to do a comprehensive search of all of the retrospective studies on TVT?
A. No.
Q. In terms of the work that you were doing, did you direct anybody to look for all of the prospective studies on TVT?

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A. No.
Q. And in terms of the studies that you did, did you ask anyone to look at all of the randomized controlled trials available on TVT?
A. No.
Q. How about multicenter. You know what a multicenter study is, correct?
A. Yes.
Q. Means there's multiple hospitals doing the same procedure to essentially rule out the contribution of physician error as a -- or physician contribution to the result, correct?
A. Yes.
Q. It removes that as a confounding factor, true?
A. Yes.
Q. Did you do any, or ask for a comprehensive review of the randomized controlled multicenter studies to be done on TVT?
A. No.
Q. And to your knowledge, were any comprehensive reviews conducted on any of those areas that I just asked you about?
A. No.

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Q. And would it be true to say that your opinions under 3.3 do not rely upon a comprehensive review of the literature as we've just described it?
MR. HUTCHINSON: Object to form. Mischaracterizing the testimony, Counsel.
A. The way you describe comprehensive, no.
BY MR. ORENT:
Q. Okay. And would you agree that you are not an expert on the peer-reviewed literature regarding the safety and efficacy of the TVT device?
MR. HUTCHINSON: Object to form.
A. Correct.
BY MR. ORENT:
Q. Okay. Now, the Nilsson study, that's a study that was provided to you by Ethicon, is that correct?
A. It was, yes.
Q. Okay. Now, were you aware that the original authors of that study began -- or the study that began 17 years earlier, the original named author had since passed away? Did you know that?

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A. No.
Q. Okay. Well, Nilsson is ultimately the guy who took on the role of that.
But were you aware that that series of studies that went over a 17-year period included provisions in the contract for those studies that payment would only be issued if no new complications were determined to be found in each of the interval periods?
MR. HUTCHINSON: Form.
A. No.
BY MR. ORENT:
Q. Would you question a study where the authors were paid to not find new adverse clinical outcomes?
MR. HUTCHINSON: Form.
A. Possibly.
BY MR. ORENT:
Q. Did Ethicon advise you that this study ultimately culminated in paying the authors more than $2 million?
A. No.
MR. HUTCHINSON: Form.
BY MR. ORENT:
Q. Would that be information that you

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would have wanted to know?
A. I don't think it would change my opinions.
Q. Would the fact that this was a -- well, let me ask you this.
What's the prior study -- before the 2013 cohort, when is the time prior, immediately prior to that that they looked at the study? How many years had passed? If this is 17 years, there was one at how many years?
A. I can't remember.
Q. Does 11 sound right to you?
A. 10 or 11.
Q. Okay. And between year 11 and year 17, how many new complications were found?
A. I can't remember. I'd have to look that up.
Q. You would agree, though, that there were new complications found, weren't there?
A. Actually I don't recall, but I don't believe any of them indicated cytotoxicity.
Q. And would erosion indicate cytotoxicity to you?
A. I don't know.
Q. Do you know what erosion is?

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A. Is that -- not specifically.
Q. Okay. Well, were you aware -- I looked at your -- I spent some time going over your material that we looked at, your reliance list, and I didn't see anything by Dr. Klosterhalfen. Do you know who Dr. Klosterhalfen is?
A. No.
Q. Do you know who Dr. Klinge is?
A. Klinge?
Q. Klinge, K-L-I-N-G-E.
A. No.
Q. Were you aware that Dr. Klosterhalfen and his group had evaluated from the 1990s forward thousands of mesh pieces, mesh explants, and published on their findings?
A. No.
Q. Were you aware that -- would that be a line of evidence that you would want to see in making cytotoxicity determinations in terms of what pathologists were finding inside human explants?
MR. HUTCHINSON: Object to form.
A. If they were reporting clear evidence of cytotoxicity, yes.

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BY MR. ORENT:
Q. Okay. And did you do a comprehensive search of prepared reviewed literature for mesh excisions, and pathology of mesh, those sort of things?
A. No.
Q. Would you agree with me that in assessing the human cytotoxicity of mesh that an understanding of human pathology and the human in vivo response is more important than understanding the animal in vivo response?
MR. HUTCHINSON: Form.
A. It is more relevant to the question. However, you cannot simply insert mesh into a woman to see what happens and to evaluate cytotoxicity, you can only go by the studies that have been conducted on women whose doctors recommend that they have this procedure for the benefits of the procedure. So you can only look at those women once they have had the procedure and look for evidence of adverse effects, such as cytotoxicity.
BY MR. ORENT:
Q. Now, do you know what the universe of, for example -- strike that.

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Why might a woman with a TVT device have that device explanted?
A. I'm not a doctor, but I suppose if it was giving her complications.
Q. Specifically what type of complications?
MR. HUTCHINSON: Objection. Counsel, this is outside the bounds of her report.
A. I'm sorry.
BY MR. ORENT:
Q. Are there particular complications that you would expect to see that evidence cytotoxicity?
A. Necrosis, and impaired wound healing.
Q. And do you know what the peer-reviewed medical literature reports in terms of necrosis in individuals implanted with TVT?
A. Among the studies I reviewed, necrosis was not mentioned as an endpoint.
Q. Did you specifically look to the peer-reviewed literature, that vast universe of case studies, case series, retrospective and prospective, as well as RCTs and multi-centered studies, did you specifically look for necrosis in any of those?

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A. I believe I did a search of TVT and cytotoxicity, and did not find any in the -- anything in the peer-reviewed literature.
Q. So I'm a lawyer, when I do research, it's a big part of what I do, I take the term that I want and I put a little circle around it and I draw all these crazy lines, almost like a little sun, I think of all the different synonyms for the word that I'm looking for. Did you do that same thing with cytotoxicity and TVT?
MR. HUTCHINSON: Object to form.
A. I believe I did after the literature search.
BY MR. ORENT:
Q. Okay. So what terms did you use?
A. Necrosis, and wound healing.
Q. And how many articles on wound healing problems with mesh did you find?
A. Well, no, I didn't do a literature search with that. Just to come to my opinions, I evaluated whether there was impaired wound healing such as in the in vivo studies, and took note of it in the clinical studies that I reviewed as well.

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Q. I see.
So you didn't actually search PubMed, for example, for necrosis, or for delayed wound healing, is that correct?
A. Right.
Q. Okay. If I went on PubMed and did those searches, do you have any idea how many articles I would find?
A. No.
Q. Do you know what the most common complication associated with the TVT device is?
A. No.
Q. Do you know whether or not the most common complication of TVT experienced in women correlates at all with cytotoxicity?
A. No.
Q. One of the documents that you reviewed was an Ethicon summary of literature, correct?
A. What type of literature?
Q. The Ethicon 2013 conducted a clinical review of 152 randomized controlled trials.
A. Yes.
Q. Did you do anything to verify the comprehensivity of that?
A. No, I just based it on what they

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stated in this report.
Q. So Ethicon still sells TVT, right?
A. As far as I know.
Q. They make money by it, right?
A. I'm sure they do.
Q. Okay. Make a lot of money, probably?
A. I don't know.
MR. HUTCHINSON: Objection. Outside the scope of her report, Counsel.
BY MR. ORENT:
Q. And it's in their vested interest to have a body of literature that supports keep selling this device, right?
MR. HUTCHINSON: Same objections. Foundation.
A. I suppose.
MR. HUTCHINSON: We don't want you to guess or speculate. I think he'll admit that.
THE WITNESS: Okay.
BY MR. ORENT:
Q. Now, you did nothing to verify the accuracy of that literature review, is that correct?
A. Correct.
Q. Now, in your report you talk about

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weight of the evidence approach.
A. Yes.
Q. And you use Bradford Hill as an example, right?
A. Yes.
Q. And really when you think about Bradford Hill, you look at causality; that is, can this substance cause this, right?
A. Right.
Q. And you narrowly defined the issue of is TVT cytotoxic here, right? That's how you defined the issue?
A. Yes.
Q. Now, it seems to me you -- the lines of evidence that you cite in your report are 3-fold, correct?
A. Yes.
Q. They're in vitro studies. And we've discussed those, correct?
A. Somewhat, yes.
Q. And the in vitro studies are -- do show that there is some cytotoxicity, correct?
A. Yes, in vitro.
Q. Okay. And we discussed in vivo, correct?

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A. Yes.
Q. And we discussed that there are only five in vivo studies conducted by Ethicon, correct?
A. That I'm aware of, yes.
Q. That you're aware of.
And you don't know how to correlate those with the human experience, correct?
MR. HUTCHINSON: Object to form.
A. Not from a pathology standpoint.
BY MR. ORENT:
Q. Okay. And we discussed the third, which would be the literature, correct?
A. Human literature?
Q. Human literature, correct?
A. Yes.
Q. And that you didn't do a comprehensive literature review, correct?
MR. HUTCHINSON: Object to form.
A. Correct.
BY MR. ORENT:
Q. And you didn't look at pathology, correct?
A. Right. I don't have expertise in that.

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Q. Now, when you do Bradford Hill, you want to look at all available lines of evidence. So, for example, you would look at everything from large scale epidemiological studies, right?
A. Yes, if they're available.
Q. To human case studies, to human series, correct?
A. We don't always look at those in toxicology. The weight-of-evidence analyses that I've done, including those on Exhibit 9, the epidemiology studies would be more informative than the case reports.
Q. You do look at various types of cell studies, cultures, and things like that, right?
A. Yes.
Q. You look at some animal studies, where available, correct?
A. Yes.
Q. And then you look at all of the evidence together, and you form an opinion, correct? Is that essentially how Bradford Hill works?
A. Well, that's how weight-of-evidence works, yes. And you can use the Bradford Hill considerations within that to tie the evidence

together, yes.
Q. Would you agree with me that really in this case your opinions rest solely on your interpretation of the mesh in vivo studies?
MR. HUTCHINSON: Object to form.
A. No.
BY MR. ORENT:
Q. Even though we've shown that your literature review was not comprehensive?
MR. HUTCHINSON: Objection. Mischaracterizes testimony.
I don't know what literature review you're talking about, Counsel. I don't think the witness does either.
BY MR. ORENT:
Q. And even though we have discussed that, in fact, in vitro this mesh is cytotoxic, correct?
A. Yes. But in vitro results do not predict, necessarily predict what's going to happen in vivo.
Q. Now, part of being a neutral scientist is evaluating both sides of the argument, correct?
A. Yes.

Q. And you saw the reports of Dr. Elliott and Dr. Rosenzweig, correct?
A. Yes, I did.
Q. And do you know how many articles, medical articles, Dr. Elliott reviewed prior to forming his opinions in this case?
A. No, I don't.
Q. Do you know how much pathology and how many pathology reports he reviewed in terms of forming his opinion?
A. No, I don't.
Q. Do you know how many human patients he saw with mesh complications prior to forming his opinions?
A. No, I don't.
Q. Same with Dr. Rosenzweig, do you know how many patients he saw with TVT complications prior to forming his opinion?
A. No.
Q. Do you know how much pathology or pathology reports he looked at prior to forming his opinions?
A. No.
Q. Do you know what body of literature he reviewed prior to forming those opinions?

A. No.
Q. Do you know what internal corporate documents Dr. Elliott and Dr. Rosenzweig looked at in terms of forming their opinions?
A. No.
Q. Now, in terms of Dr. Iakovlev, how many of his reports have you reviewed?
A. Just one.
Q. Do you know whether or not Dr. Iakovlev has actually written in other reports about necrosis?
A. No, I don't.
Q. Do you know whether or not Dr. Iakovlev has formed opinions on bridging fibrosis?
A. No.
Q. Do you know whether or not he has formed opinions on other aspects of interactions between mesh and human tissue that might be considered cytotoxic?
A. No, but he didn't report any cytotoxicity in this particular report.
Q. And have you read Dr. Iakovlev's peer-reviewed published articles on mesh?
A. No.

MR. ORENT: Why don't we take a short five minute break.
THE VIDEOGRAPHER: Going off the record. The time is 12:09.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: Back on the record. The time is 12:31.
BY MR. ORENT:
Q. I asked you this question with regard to in vivo, but let me ask it with in vitro.
You yourself, do you do in vitro testing?
A. No.
Q. Now, if we look at, in your report, data Table A.2 -- I'm sorry, A.3, I notice that there's no footnotes there, and there's a whole host of footnotes on the shorter A.1 and A.2. Why is it that there's no footnotes?
A. I didn't think there was anything necessary to footnote. The footnotes in Tables A.1 and A.2 were just clarifying whether they were ISO guideline studies.
Q. Okay. A few other questions for you.
With regard to your work at Gradient, you're not a principal, correct?

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A. Correct.
Q. Are you in line to be a principal?
A. Yes, I am.
Q. And at what point in your career, how many more years, or when do you come up for evaluation for becoming a principal?
A. Well, to become a principal at Gradient, it's dependent upon how much revenue you bring in.
Q. Okay. And what is the amount of revenue that is considered enough to become a principal?
A. It might be different for different people, but I believe the general number is 100,000.
Q. Okay. Is that per year, or --
A. Yes.
Q. And do you reasonably believe that you're going to become a principal this year, at the end of the year, or next year?
A. This year, no.
Q. Now, with regard to the structure here, do you have a principal who is your supervisor?
A. No.

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Q. How does that work? Who is your boss?
A. Well, in a case like this where I'm hired, I'm the boss.
Q. But in terms of structure within Gradient, who do you report to?
A. Yes, I do have a manager who is a principal here.
Q. And who is that?
A. His name is Kurt Herman.
Q. And does he evaluate your work at the end of every year?
A. Yes.
Q. And in terms of the projects that you take on, do you need to get Kurt's approval?
A. No.
Q. Do you need to get any sort of corporate approval?
A. No. The only thing we do is we do a confidentiality check before agreeing to do work.
Q. And do you individually -- I know that your billing rate is 265 an hour, is that right?
A. Yes.
And the last thing I said, I meant to say a conflict of interest check, not a

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confidentiality check. Sorry.
Q. I understood that that's what you meant.
A. Yes.
Q. Your rate is 265 an hour, correct?
A. Yes, it is.
Q. Do you directly receive any portion of your billings?
A. Principals at Gradient do receive a percentage of the revenue of projects that they bring in.
Q. Okay. So in terms of this particular project, since you're not technically a principal yet, do you receive a percentage of the total billings?
A. Yes.
Q. What's that percentage?
A. I actually don't know.
Q. Okay. And that's a percentage of not just the work that you do, but the work that's assigned out and billed under your project, is that right?
A. I don't know.
Q. Do you know, is it greater or less than 10 percent?

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A. I don't know.
Q. Okay. We just took what I thought was going to be a short break, ended up being a little bit longer. Did you have the opportunity over the course of the break to talk to your counsel?
A. Yes, I did.
Q. Did you talk about the substance of your testimony?
A. Substance? We did talk about the testimony.
Q. Okay. Did you review any documents?
A. No.
Q. Did you prepare questions that you were going to be asked going forward?
A. I did not, no.
Q. Were you asked -- basically were you told what questions you would be asked?
MR. HUTCHINSON: Objection. Counsel, that's work product. Instruct the witness not to answer.
BY MR. ORENT:
Q. Are you going to stand by that advice?
A. Yes.
Q. But you did talk about the substance

of what we're discussing here today, correct?
A. Some of it.
MR. ORENT: Okay. All right. I'm going to maintain an objection to your last instruction on the record and reserve all my rights accordingly.
Subject to that, I am done, and obviously also subject to my right to redirect.
EXAMINATION
BY MR. HUTCHINSON:
Q. Dr. Prueitt, my name is Chad Hutchinson, I have the privilege of representing Ethicon and Johnson & Johnson.
Walk us through your education, please.
A. I received a bachelor of science degree in biology from Pacific Lutheran University. And then I received a Ph.D in molecular biology from the University of Texas Southwestern Medical Center at Dallas. Then I was a post-doctoral fellow at the National Cancer Institute for five years. Then a staff scientist at the Fred Hutchinson Cancer Research Center for one year.
Q. And what did you do as a staff

scientist?
A. I managed and conducted studies investigating prostate cancer biomarkers.
Q. Through the course of your education, experience, have you done toxicology work?
A. Yes, I have.
Q. And would that be reflected in your CV?
A. Yes.
Q. Would you tell the jury about your toxicology work, please?
A. At the National Cancer Institute I studied the effects of smoking and nicotine on prostate cancer.
Q. Anything else?
A. No.
Q. Are you board certified in anything, Dr. Prueitt?
A. Yes, I'm board certified in toxicology.
Q. What does it mean to be board certified in toxicology?
A. So first it requires a certain combination of education and experience. For example, for someone with a Ph.D, it would

require an additional three years of working toxicology experience, and then for a master's degree it would require seven years. And so that combination of education and experience qualifies you to take the exam to be board certified.
So then I sat for an exam that is -- that covers toxicology, every aspect of toxicology, very comprehensive exam, for a day and a half, and so I passed that exam. And then to keep my board certification, each year I have to do either -- well, I have to do a certain number of toxicology-related activities, such as attend conferences, publish papers, take courses, things like that.
Q. And, Doctor, you mentioned publishing papers. Have you published any peer-reviewed journal articles regarding toxicology?
A. Yes, I've published quite a few.
Q. Are those reflected in the CV that the Plaintiffs' lawyer attached as Exhibit 1 to your deposition?
A. Yes, they are all listed there.
Q. And have you spoken about toxicology issues?

A. Yes.
Q. And that would be presentations in front of peers?
A. Yes.
Q. Are those references and presentations included in your CV that Plaintiffs' lawyer marked as Exhibit 1 to your deposition?
A. Yes, they are.
Q. I notice on your CV there's a Ph.D behind your name, is that correct?
A. Yes.
Q. What does that mean? What do you have a Ph.D in?
A. My Ph.D is in molecular biology and human genetics.
Q. And do you use that discipline in your field, in toxicology?
A. Yes.
Q. I also noticed behind your name D.A.B.T.. What does D.A.B.T. stand for?
A. Diplomate of the American Board of Toxicology, so that's indicating my board certification.
Q. Now, Dr. Prueitt, let's look at your expert report that's marked as Exhibit 1 to your

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deposition. Do you have that in front of you?
A. Yes.
Q. And turn with me, please, to Page 18 of your report.
Are you there?
A. Yes.
Q. And Page 18 lists reliance documents, correct?
A. Yes.
Q. What are reliance documents?
A. These are the documents that I reviewed, and some of which -- and some of them I cited in my report, and so I reviewed these and used them to come to my opinions.
Q. And, Dr. Prueitt, I'll represent to you that there are 72 different documents under this heading. Does that sound about right to you?
A. It does. They're not numbered, so I can't check, but that sounds right.
Q. You were asked questions about whether you read all of these documents before beginning your expert report. Do you recall that line of questioning?
A. Yes.

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Q. And, Dr. Prueitt, I believe you testified that you didn't read some of these documents before you began your expert report, is that right?
A. Correct.
MR. ORENT: Objection to form.
BY MR. HUTCHINSON:
Q. Let's talk about after you started working on your expert report. Have you had an opportunity to review all of the reliance documents listed in Exhibit 1 to your deposition?
A. Yes.
Q. And when did you do that?
A. After I started the report.
Q. Have you reviewed these documents during the course and scope of your work on this particular project?
MR. ORENT: Objection.
A. Yes.
BY MR. HUTCHINSON:
Q. And is that something that you as a toxicologist would normally do in your practice?
A. Yes.
Q. Let's turn to Page 12 and 13 of your

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report, starting on Page 12, and let me know when you're there.
A. I'm there.
Q. Section 3.2.1 is "The results from in vivo implantation studies indicate no cytotoxicity." Did I read that correctly?
A. Yes.
Q. Is this part of your report?
A. Yes.
Q. What does that mean?
A. That means that after I reviewed the results of in vivo implantation studies of Prolene sutures in mesh that I came to the conclusions, based on those studies, that the TVT device does not cause cytotoxicity in in vivo animal studies.
Q. And for the benefit of the jury, what is an in vivo animal study?
A. It's a study conducted in a whole animal.
Q. What is an in vitro study?
A. That's a study conducted outside of a whole animal in a closed system, such as in a petri dish.
Q. Can you -- strike that.

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You were asked whether or not on Page 12 and 13 of your report you summarized the findings of original authors.
Do you remember that?
A. Yes.
Q. And is that what you did?
A. Yes.
MR. ORENT: Object.
BY MR. HUTCHINSON:
Q. Is that part of the weighted evidence approach that you as a toxicologist use to reach your opinions?
A. Yes, we commonly do that. We have to rely on the study reports of others, the authors of the studies that we review. We are not a testing lab. This is what we do as toxicologists in consulting.
Q. Is it common for a toxicologist such as yourself to rely on work of other scientists?
A. Yes.
Q. Is that what you were doing here?
A. Yes.
Q. Dr. Prueitt, you were asked whether or not you conducted a comprehensive review of all human case studies, retrospective studies,

prospective studies, and randomized control trials. Do you remember that line of questioning?

A. Yes, I do.

Q. Did you need to do that?

A. No.

Q. Why not?

A. Because I reviewed -- I felt that I reviewed a sufficient number of studies to come to my conclusions. And as a toxicologist it's not something that we normally do to -- is review case studies. It's better to rely on epidemiology studies, because they actually will show whether there's a statistically significant effect of a chemical or treatment, whereas case studies do not show that.

Q. Tell the jury what type of studies that you as a toxicologist relied on in reaching your opinions.

A. I relied on in vitro cytotoxicity studies of Prolene mesh. I relied on in vivo -- or the in vivo implantation studies of the Prolene mesh from TVT. I relied on suture studies of the Prolene sutures. And I relied on long -- or clinical studies with long-term

follow-up of women who were implanted with TVT.

Q. And what do those studies tell you as a toxicologist?

MR. ORENT: Objection.

A. All together the results of all of those studies indicate that the TVT mesh is not cytotoxic in vivo and is not cytotoxic -- or does not show evidence of cytotoxicity in humans.

BY MR. HUTCHINSON:

Q. Let's talk about the literature and the documents that you reviewed.

Did you bring three notebooks with you here today?

A. Yes, I did.

Q. And marked as Exhibit -- was it 4 to your deposition?

MR. ORENT: It's 3.

BY MR. HUTCHINSON:

Q. Marked as Exhibit 3 to your deposition is a document. Have you seen that document before?

A. Yes.

Q. Would you tell the ladies and gentlemen of the jury what Exhibit 3 represents?

A. This represents all of the documents that I specifically cited in my report.

Q. And did you review those documents that you specifically cited in your report?

A. Yes, I did.

Q. Can you give us an idea of how many documents there are?

A. There are -- I cited 76 documents.

Q. And did you bring those documents with you here today?

A. Yes.

Q. Dr. Prueitt, you testified earlier that you did not do a comprehensive literature review. Do you remember that?

A. Yes.

Q. What did you mean by that?

A. I meant by his definition of comprehensive.

Q. Who is "his"?

A. Counsel.

Q. For the Plaintiff?

A. For the Plaintiff.

Because I answered that question shortly after he described what he meant by comprehensive literature review, which included

case studies and other types of studies that I did not rely on and do not normally rely on as a toxicologist.

Q. And, Dr. Prueitt, I believe you testified earlier that you're not an expert on peer-reviewed literature about the safety and efficacy of TVT. Do you remember that testimony?

A. Yes.

Q. Do you need to be an expert on the peer-reviewed literature of that?

A. Not to form opinions on whether TVT is cytotoxic.

Q. And is that what you were asked to do in this case?

A. Yes.

Q. Is a generally accepted methodology of a toxicologist to review all of the safety and efficacy literature of a device when studying only cytotoxicity?

MR. ORENT: Objection.

A. No, and particularly not the efficacy.

BY MR. HUTCHINSON:

Q. Why not?

A. Because that has no bearing on the

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potential cytotoxicity of the device.
Q. Dr. Prueitt, walk us through the methodology that you used as a toxicologist to reach your opinions in this case.
A. Okay. First I reviewed the documents that were given to me, the in vitro cytotoxicity studies, and the related documentation such as by Dr. Barbolt that discusses these studies. Also, the in vivo cytotoxicity studies that were provided for the sutures and the mesh, because I did not find any studies evaluating potential cytotoxicity of TVT or even Prolene in the peer-reviewed literature.
Q. And then what did you do?
A. And then I also looked at the -- looked at clinical studies of TVT for -- with follow-up of ten years or more to look for potential adverse effects of TVT that might be related to cytotoxicity.
Q. And what do those studies show, Dr. Prueitt?
A. Those studies showed that there were no adverse effects specifically related to cytotoxicity in the women implanted with TVT.
Q. Did those studies show any evidence of

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necrosis?
MR. ORENT: Objection.
A. Not that I saw, no.
BY MR. HUTCHINSON:
Q. And, Dr. Prueitt, as a toxicologist, what does necrosis tell you about cytotoxicity?
A. It can be an indication of cytotoxicity. However, the presence of necrosis may not definitively indicate that the cytotoxicity occurred from the exposure, it could have been due to other complications, of the surgery itself, or if there was a -- some other type of adverse effect from the surgery, such as a large amount of inflammation. It could cause cells to die. There could be mechanical cell death from encountering the edge of the device, I would think.
Q. Dr. Prueitt, I'll apologize if I interrupted you, but had you finished walking us through your methodology that's used in reaching your toxicology opinions?
A. No.
Q. Okay. What else did you do?
A. Well, I didn't mention this -- all the types of studies that I reviewed and that I did

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a literature search and didn't find any other in vitro or in vivo studies, or clinical studies specifically related to cytotoxicity of TVT. But -- so then I laid out the in vitro and in vivo studies in the tables that are at the back of my report, and looked at all the evidence together, considered the relevance of in vitro results to the situation in vivo and in humans specifically, and then determined that, you know, the weight of the evidence should lean towards the in vivo studies and the clinical studies because those are the most relevant to humans. And those -- because those studies did not show evidence of cytotoxicity specifically from exposure to the TVT device, then I formed my conclusions.
Q. And, Dr. Prueitt, is this the methodology that you used -- strike that.
Is the methodology you used the generally accepted methodology employed by a toxicologist in reaching the opinions you reached in this case?
MR. ORENT: Objection.
A. Yes, it is. I've used it before, and my colleagues use it as well.

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BY MR. HUTCHINSON:
Q. And, Dr. Prueitt, you mentioned earlier that you created some tables that are in Exhibit 1 to your deposition, is that correct?
A. Yes.
Q. And what do those tables tell us?
A. The tables lay out the general methodology and the results of the in vitro and in vivo studies that I reviewed.
Q. And, Dr. Prueitt, would that allow another scientist to repeat and verify your work?
A. Yes. Another scientist could look at these tables, or they could make their own tables of these studies and use them to come to their conclusions.
Q. Dr. Prueitt, did you search PubMed for necrosis and wound healing?
A. No, I did not.
Q. Did you need to do that?
A. No, I did not need to do that to come to my opinions.
Q. Why not?
A. Because I felt that the clinical studies that I reviewed which had follow-up of

ten years or more in women with the TVT device and did not show evidence of cytotoxicity were enough to help me reach my opinions. And also the presence of necrosis and wound healing difficulties may not necessarily be caused specifically by cytotoxicity.

Q. Doctor, you testified earlier that some of the studies in vitro were positive. Do you remember that?

A. Positive for cytotoxicity, yes.

Q. Does the analysis stop there when reaching an opinion about cytotoxicity of a material?

A. Absolutely not. You also have to --

Q. Why not?

A. Because results in vitro cannot be directly extrapolated to what will happen in vivo. You have to also evaluate in vivo studies and human studies if they are available.

Q. Why can those results not be extrapolated from a scientific standpoint?

A. Because those results were based on putting either an elution from the mesh or the mesh itself directly on a single cell type, and with -- so it's an artificial situation, it's

not anywhere near the same as what's in the body. And so in vitro tests like this are only used as an initial screening test, they are never used to show a definitive affect.

Q. Dr. Prueitt, I want to go back to the methodology that you used to render your opinions. Have you used the methodology that you used here before?

A. Yes.

Q. Have your colleagues used the same methodology before today?

A. Yes.

Q. Why did you use this type of methodology?

A. Because it is the standard methodology for evaluating potential adverse effects and causation that's used by toxicologists both in, you know, a regulatory -- by regulatory toxicologists, as well as in the peer-reviewed literature.

Q. Dr. Prueitt, you were asked by the Plaintiffs' lawyer whether or not you did the in vitro or in vivo testing. Do you remember that line of questioning?

A. Yes.

Q. Dr. Prueitt, do you need to be the one who physically does the in vitro or in vivo testing to reach sound toxicology opinions in this case?

A. No.

Q. Why not?

A. Because I can review the studies and see the results and interpret them based on the study. I don't have to be, you know, the one actually conducting the study to be able to interpret it.

MR. HUTCHINSON: I don't have any more questions right now. Thank you for your time, Dr. Prueitt.

EXAMINATION

CONTINUED BY MR. ORENT:

Q. Doctor, I have some follow-up questions for you.

First of all, Doctor, in order to evaluate cytotoxicity in humans related to the TVT device, specifically what clinical manifestation would you expect to find in the literature to determine whether or not there was evidence of cytotoxicity? What would the clinical picture be?

A. Right. There could be necrosis. There could be affects on wound healing.

Q. How about -- so delayed wound healing?

A. Yes, that could be evidence of cytotoxicity.

Q. What about ulceration?

A. I don't know.

Q. Okay. You previously said you don't know what erosions are, correct?

A. Right.

Q. So you don't know if an erosion could be a sign of cytotoxicity, correct?

A. No, I don't know.

Q. Okay. How about extrusion, do you know what an extrusion is?

A. Not definitively.

Q. Okay. So if you're looking in the clinical literature and you see a report of extrusion, to you do you know whether or not that is a sign of cytotoxicity?

MR. HUTCHINSON: Objection.

Counsel, she just told you she didn't know what it was.

BY MR. ORENT:

Q. You can answer.

A. No, I don't know specifically what that is, but I know that necrosis and impaired wound healing would be most likely what you would visualize if there was cytotoxicity.

MR. ORENT: Move to strike the last portion.

BY MR. ORENT:

Q. Now, when an individual patient comes in and complains of -- let me see, scarification is another example of cytotoxicity, correct?

A. Not that I'm aware of.

Q. Fibrotic reaction?

A. Not that I'm aware.

Q. Okay. How about banding?

A. Not that I'm aware.

Q. Okay. Now, with regard again to the mesh in cytotoxicity, do you know -- I understand that you were looking for the words necrosis somewhere, but what would the physical presentation of a patient be who complains of something that ultimately may lead to a diagnosis of necrosis? What would that look like?

A. I don't know. I'm not a medical doctor.

Q. Okay. So if you were looking at the initial -- in any of these studies, for example Nilsson, do you know, the complications that arose between 11 and 13 years in Nilsson, did they send the pathology out for microscopy and further diagnosis to determine whether or not necrosis was present?

MR. HUTCHINSON: Object to form.

A. They report that there were no serious long-term TVT-induced adverse effects, so I don't think that matters for my opinions.

BY MR. ORENT:

Q. Okay. Well, you looked at the data tables associated with Nilsson 2013, correct?

A. Yes.

Q. And you're aware that there were new complications that was reported in that period, correct?

A. I don't remember.

Q. Okay. Well, would you have -- I mean as part of your standard practice, this is one of the few named studies that you looked at, would you have looked at the data tables in Nilsson?

A. Yes.

Q. Okay. So if erosion were listed as something that was new between years 11 and 17, would you have wanted to investigate what exactly that meant?

A. No. I was looking for something that would indicate, clearly indicate cytotoxicity.

Q. And so prior to beginning this process, prior to looking at the human clinical evidence that you've cited here, did you talk to a urogynecologist?

A. No, I don't think I needed to do that.

Q. Did you talk to a pathologist to find out what the clinical manifestation of these sort of things might be?

A. No, I didn't need to do that.

Q. Okay. Now, in terms of necrosis, have you ever seen in a medical implant study a diagnosis of something like necrosis?

A. No, I haven't.

Q. Okay. Do you know whether or not necrosis is something that's seen at the microscopic level?

A. Yes, it would be.

Q. Okay. And so do you know whether or not the clinical presentation, that a clinician

would ever call it necrosis, or do you think that that would later be made by a pathologist?

MR. HUTCHINSON: Objection. Outside the bounds of her report.

BY MR. ORENT:

Q. Do you know?

A. I don't know.

Q. But that would be important, wouldn't it, in determining whether or not you're likely to see the term necrosis in a clinical study, wouldn't it?

A. I don't know.

Q. Who makes the diagnosis of necrosis?

A. I don't know for sure.

Q. Okay. Now, we talked about the studies. You just mentioned you focus on studies with -- that were present at least ten years out, correct?

A. Yes.

Q. Okay. And do you know what percentage of complications occur before ten years?

A. No, I don't think that matters for my opinions on cytotoxicity.

Q. Okay. Now, in order for you to determine that a substance is cytotoxic, does it

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need to show cytotoxic properties in every single woman?
A. No, because humans are variable.
Q. Okay. So if the greatest percentage of complications occur between year one and, let's say, year seven or eight or nine, wouldn't you want to look at the complications that occur in that period of time to determine if there's evidence of cytotoxicity?
A. Well, I mean I also looked at the clinical literature review of 152 randomized controlled trials, you know, that Ethicon did. So, you know, to come to my opinions about cytotoxicity I -- you know, if there were issues with cytotoxicity of the device, those issues should be long-term. I mean if this is implanted and it's causing cytotoxicity, it should cause cytotoxicity all the time, and you should be able to -- that would -- that should be a clear adverse effect. And so if this is a cytotoxic material, you would expect to see it in a large number of women.
Q. Are you aware that there's 100,000 mesh lawsuits in existence right now?
MR. HUTCHINSON: Form.

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A. No, I don't know the number.
BY MR. ORENT:
Q. Is that a large number?
A. I don't know.
Q. Let me ask you -- you didn't actually answer my question, my last question, so let me just go back and ask it again.
In order for you to determine that the cyto -- excuse me.
If the greatest percentage of complications occur between year one and, let's say, year seven or eight or nine, wouldn't you want to look at the complications that occur in that period of time to determine if there's evidence of cytotoxicity? It's a yes or no question.
A. Yes, and I did by looking at the clinical literature review.
MR. ORENT: Move to strike after the word "yes."
BY MR. ORENT:
Q. The clinical literature review was not a clinical literature review conducted by you, correct?
A. Correct.

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Q. And you'd agree with me that the dose makes the poison, right?
A. Generally, yes, that's standard toxicology tenet.
Q. And, in fact, you cite it in your report, don't you?
A. Yes.
Q. So understanding that the dose makes the poison, how do you account for that in the studies that look at suture versus mesh?
A. Well, the mesh is larger than the sutures, so if there were chemicals leaching out of the material, there would be -- it would be in a higher concentration in the mesh versus the sutures. However, the studies -- the in vivo studies of both the sutures and the mesh show no cytotoxicity.
Q. Well, would you agree with me that all of the in vivo mesh cytotoxicity studies are all short-term, correct?
A. In vivo studies?
Q. Mm-hmm.
A. No. There was a study of up to 182 days, that's considered a chronic study.
Q. Okay.

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A. So that is not considered short-term.
Q. That's the only one?
A. And then the 91-day study below that, that's actually considered chronic as well.
Q. Okay.
A. And then the others are considered subacute, less than 30 days.
Q. So we're talking 182 days, that's roughly half a year, correct?
A. Yes.
Q. Do you know what percentage of women with mesh complications develop those complications after the first six months?
A. No, but I don't think that matters. And the lifespan of a rat is much shorter, and so I don't know -- that's not directly comparable.
Q. So how do you -- what is the established peer-reviewed methodology for taking a rat study and equating it to a human?
A. Well, generally you look to see if there are known -- what the differences in physiology are.
Q. We already discussed one article today about the appropriate types of animals to be

used in the pelvic mesh context. Are you aware of an entire body of literature that exists on the very issue of animal selection for extrapolation of information to the pelvis?

A. No. But I still don't, you know, think that that would necessarily change my opinions.

Q. You didn't research that, right?

A. No, it's not something I researched. But I --

Q. I'm sorry, I have one other question.

MR. HUTCHINSON: I'm sorry, Dr. Prueitt, were you finished with your answer?

A. Yeah, I wasn't quite finished.

The fact that the literature I reviewed for the human clinical studies doesn't indicate cytotoxicity, you know, based on that, based on what I found from that, you know, showing a lack of cytotoxicity in women, so the potential differences in physiology among the different species, you know, it may not matter.

BY MR. ORENT:

Q. So when you were talking about your opinion relative to women in the human clinical data earlier, you said something. You said that

your opinion is that there's no evidence of cytotoxicity in women. Do you recall saying that?

A. Yes.

Q. Now, I want to just clarify. Is your opinion the TVT is not cytotoxic in women, or is it that you have seen no evidence of cytotoxicity in women?

A. I want to be consistent with my report.

Q. I'll let you go to your report in a second.

Can you answer that question without looking at your report, Doctor?

A. No, I just want to be consistent with it.

Q. So you cannot answer that without looking at your report?

MR. HUTCHINSON: Counsel, she made reference that she wants to look at the report.

MR. ORENT: That's fine.

BY MR. ORENT:

Q. I just want the record to reflect that I've asked that question to what your opinion is before you review your report. And if you need

that to look at it, that's fine, but I want the record to reflect that you need your report to answer that question.

MR. HUTCHINSON: Let the record reflect the witness has told you she wants to be consistent.

A. The clinical studies show no evidence of cytotoxicity, the clinical studies I reviewed.

BY MR. ORENT:

Q. Okay. So is your opinion that you have seen no evidence of cytotoxicity, or is it that the TVT is not cytotoxic?

A. Well, the fact that I've seen no evidence of cytotoxicity in women combined with the other evidence that I evaluated leads me to conclude that the weight of the evidence indicates that the TVT is not cytotoxic in women to a reasonable degree of scientific certainty.

MR. ORENT: Okay.

MR. HUTCHINSON: We don't have any further questions.

Thank you, Dr. Prueitt, for your time.

MR. ORENT: Thank you.

THE VIDEOGRAPHER: Going off the

record. This concludes the deposition of Dr. Prueitt of October 22nd, 2015. The time is 1:15.

(Whereupon, the deposition was concluded.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 22nd day of October, 2015, at 9:48 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 24th day of October, 2015.

____
MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

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It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, __________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
ROBYN LYN PRUEITT, Ph.D., D.A.B.T. DATE

Subscribed and sworn
To before me this
______ day of ________________, 20____.
My commission expires: ________________

____
Notary Public

LAWYER'S NOTES

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